UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA

THE UNITED STATES OF AMERICA, and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, and WASHINGTON; THE DISTRICT OF COLUMBIA; THE COUNTY OF ALLEGHENY; and THE CITIES OF CHICAGO, NEW YORK, and PHILADELPHIA, *ex rel.* JOEL STEVENS Plaintiffs, *v.* ATRICURE, INC., ST. HELENA HOSPITAL, AND ADVENTIST HEALTH Defendants.	Civil No. **3:17-cv-10** **THIRD AMENDED COMPLAINT**

Plaintiff and *qui tam* Relator, Joel Stevens, by and through his attorneys, The Brooks Law Firm, LLC, the Rabon Law Firm, PLLC, and Lewis & Roberts, PLLC, alleges for his Third Amended Complaint as follows.

I. INTRODUCTION

1. Relator brings this Third Amended Complaint seeking damages and penalties against Defendants AtriCure, Inc. ("AtriCure"), St. Helena Hospital ("St. Helena"), and Adventist Health ("Adventist") (collectively "Defendants") pursuant to the federal False Claims Act, 31 U.S.C. § 3729 *et seq.* ("the FCA"), and analogous state, municipal, and county false claims acts to recover government funds illegally obtained by Defendants.

2. The claims in this case arise from AtriCure's aggressive, brazen, and ongoing promotion of its medical devices through the offer and payment of illegal kickbacks to surgeons, electrophysiologists, and health care facilities, including hospitals and clinics. In a Corporate Integrity Agreement entered into between AtriCure and the Office of Inspector General, U.S. Department of Health and Human Services in January 2010, AtriCure promised that it would stop the unlawful promotion of its medical devices and associated procedures. It has not kept those promises.

3. From at least 2011 to the present (the "Relevant Period"), AtriCure, with the knowledge, involvement and participation of St. Helena and Adventist, engaged in a nationwide, interconnected and ongoing kickback scheme to cause false claims for payment to be submitted to and paid for by federal, state, city and county government healthcare programs.

4. The Defendants individually and/or in concert offered and paid various forms of remuneration and gave other things of value to hospital, surgeon and electrophysiologist ("EPs")

customers in violation of the federal Anti-Kickback Statute (the "AKS"), 42 U.S.C. § 1320a-7b(b).

5. First, AtriCure paid kickbacks in the form of cash payments that included lucrative consulting agreements through which it paid hourly and event-based fees to select groups of surgeons and EPs. These providers in turn promoted both the on-label and off-label use of AtriCure's expensive products at conferences, trainings and patient outreach events. AtriCure additionally made cash payments to surgeons and EPs to induce them to perform off-label procedures that would expand the surgical patient population, and to appear on AtriCure's behalf at promotional events for the ostensible purpose of providing or receiving educational information. Hospitals and their affiliated physician practices that agreed to host such events were awarded cash payments from AtriCure in the guise of "educational grants." In the case of Defendant St. Helena, AtriCure additionally paid St. Helena cash remuneration in return for hosting surgical teams to perform off-label procedures onsite.

6. Second, AtriCure extended in-kind kickbacks to customers by paying third parties to perform consulting and professional credentialing and advertising services free of charge for surgeons and electrophysiologists who promoted AtriCure's products for use in off-label procedures. AtriCure's remuneration in the form of paid third-party consulting services included reimbursement services, placement of providers on the patient referral website https://www.stopafib.org/ and radio advertisements.

7. Third, AtriCure gave kickbacks to hospitals in the form of free capital equipment and free disposable medical device products, conditioned on further purchasing and/or off-label use. AtriCure's free capital equipment arrangements were routinely disguised as allegedly lawful loan agreements.

8. AtriCure paid and Defendants St. Helena and Adventist received these inducements with the requisite scienter, sufficient to establish liability as to all three defendants under the AKS and the FCA.

9. Defendants acted knowingly in carrying out the schemes described herein, because they did so with actual knowledge, deliberate ignorance, and/or in reckless disregard of the truth or falsity that such actions and conduct violated applicable federal laws and regulations.

10. Defendants' wrongful conduct resulted in the submission of millions of dollars in false claims to the Government, to the detriment of taxpayers.

11. This Third Amended Complaint is filed pursuant to F.R.C.P. 15(a)(2) with the written consent of counsel for the opposing parties.

II. PARTIES

12. Relator is a resident of Colorado. Relator holds a Bachelor of Arts degree and a computer science degree. Between 2003 and 2010, Relator worked for two medical device companies other than AtriCure.

13. From 2011 until 2016, Relator was employed by Defendants as a Regional Sales Manager. As a Regional Sales Manager, Relator was responsible for all sales and customer relationships for Defendant AtriCure in the states within his territory. Relator also managed a team of clinical specialists and ablation specialists for case coverage and training labs.

14. Defendant AtriCure is a medical device company that specializes in creating equipment used to treat atrial fibrillation. Defendant AtriCure is headquartered at 7555 Innovation Way, Mason, Ohio and operates nationwide, including in the Western District of North Carolina.

15. Defendant Adventist Health is a healthcare organization that operates approximately twenty hospitals in California, Hawaii, Oregon, and Washington. Adventist Health is headquartered at 2100 Douglas Boulevard, Roseville, California. Adventist Health operates Defendant St. Helena Hospital in Napa Valley, California.

16. Defendant St. Helena Hospital is a hospital located at 10 Woodland Road, St. Helena, California.

III. JURISDICTION AND VENUE

17. This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. The Court has supplemental jurisdiction under 28 U.S.C. § 1367 as to Relator's claims under the various state, county, and municipal False Claims Acts as alleged herein.

18. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the allegations or transactions in this Complaint. Insofar as there has been any public disclosure, Relator is the original source of the information on which the allegations of this lawsuit are based.

19. This Court has personal jurisdiction over the Defendants because at least one of the Defendants has transacted and continues to transact business in the Western District of North Carolina.

20. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), because Defendant AtriCure has transacted and continues to transact business in the Western District of North Carolina.

IV. BACKGROUND

A. Government Healthcare Programs

1. The Medicare Program

21. Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq*., established the federal Medicare health insurance program for the elderly and disabled. It is the nation's largest health insurance program and covers nearly 40 million people. Medicare is administered by the United States Department of Health and Human Services, through its agency, the Centers for Medicare and Medicaid Services ("CMS").

22. Medicare operates by authorizing payments in accordance with government-established conditions and rates for in-patient and out-patient healthcare services to "providers," such as hospitals, skilled nursing facilities, outpatient rehabilitation facilities, and home health agencies. 42 U.S.C. §§ 1395cc(a), 1395x(u).

23. Medicare Part A is hospital insurance that helps cover certain types of care provided by institutional providers within specified limits. *See* 42 U.S.C. § 1395c. Medicare Part B (Medical Insurance) covers some medical services that Part A does not cover, such as some of the services of physical and occupational therapists, and some healthcare. *Id*.

In order to participate in the Medicare program, a healthcare provider must enter into an agreement ("Provider Agreement") with the Secretary of the United States Department of Health and Human Services ("HHS"). 42 U.S.C. § 1395. After entering into a Provider Agreement, Medicare directly pays the provider a pre-determined rate for care provided to covered patients. A provider must comply with the requirements of the program in order to be eligible to receive payments from the program.

24. Under the Medicare program, "no payment may be made under Part A or Part B for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member." 42 U.S.C. § 1395y(a)(1)(A). To satisfy this standard, providers must provide, among other things, economical medical services, along with evidence that the service will be of a quality that meets professionally recognized standards of healthcare and will be supported by evidence of medical necessity and quality. 42 U.S.C. § 1320c-5(a)(1-3).

25. In order to qualify for payments by Medicare for services provided, providers must submit an enrollment application to the program on its Form CMS 855A. Among other things, the application requires providers to sign a certification that states in relevant part:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

2. <u>The Medicaid Program</u>

26. Medicaid is a federal and state funded health program, benefiting "categorically eligible" people, who are mostly low-income individuals and families. Like Medicare, it was created in 1965 pursuant to Title XIX of the Social Security Act. Under Medicaid, participating states administer state Medicaid programs that subsidize healthcare coverage for eligible residents. The individual state programs reimburse medical providers and hospitals for services rendered to program participants. The states receive federal funds to pay for Medicaid services.

27. Each state's Medicaid program must cover hospital services, 42 U.S.C. §§ 1396(a)(10)(A), 1396d(a)(12), and uses a cost reporting method similar to that used under Medicare.

28. Each physician who participates in the Medicaid program must sign a Medicaid provider agreement with his or her state. Although there are variations in the agreements among the states, all states require the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, including the fraud and abuse provisions.

29. Similar to Medicare coverage requirements, medical services must be reasonable and medically necessary in order to be subsidized by Medicaid. Claims for reimbursement presented by a provider to a state Medicaid program are subject to terms of certification. These terms require that the medical services for which the claims are sought were provided in accordance with applicable federal and state laws.

B. Applicable Law

1. The False Claims Act

30. The False Claims Act ("FCA") establishes liability to the United States for any individual who, or entity that, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," 31 U.S.C. § 3729(a)(1)(B). "Knowingly" is defined to include actual knowledge, reckless disregard, and deliberate indifference. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

31. The FCA provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval by the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 up

to $11,000 for each such claim, plus three times the amount of the damages sustained by the Federal Government. 31 U.S.C. §§ 3729(a)(1)(A) and (B).

2. The Anti-Kickback Statute

32. The federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320-7b, makes it a crime to knowingly and willfully offer, pay, solicit or receive any remuneration to induce the referral of or "to purchase, lease, order, arrange for or recommend" any good or service reimbursable under a federal health benefits program. 42 U.S.C. §§ 1320a-7b(b)(1) (referral prohibition) & (2) (purchase, lease, prohibition, etc.).

33. "Any remuneration" means any kickback, bribe, or rebate, direct or indirect, overt or covert, cash or in kind. *Id.* § 1320a-7b(b)(1).

34. AKS violations are a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both, and exclusion from federal health care programs for at least five years. *See* 42 U.S.C. § 1320a-7b. In addition to the statute's criminal penalties, the HHS Secretary has power to impose administrative penalties including exclusion and sanctions of $10,000 per kickback violation. *Id.* § 1320a-7a.

35. The statute's prohibition against knowing and willful conduct in disregard of the law extends to any arrangement where one purpose of the remuneration is to induce referrals. *U.S. ex rel. Westmoreland v. Amgen, Inc*., 812 F. Supp. 2d 39, 47 (D. Mass. 2011) (collecting cases).

36. The HHS Secretary promulgates regulations defining safe harbor practices not subject to AKS liability where the excluded practices are unlikely to result in fraud or abuse. *See* 42 C.F.R. § 1001.952; *see also Zimmer, Inc. v. Nu Tech Med., Inc.*, 54 F. Supp. 2d 850, 855 (N.D. Ind. 1999) (§ 1320a-7d(b) authorizes the HHS Secretary to issue advisory opinions on

what constitutes prohibited remuneration and whether an activity could result in sanctions or exclusion from federal health care programs).

37. The twenty-two AKS safe harbors, enumerated at 42 C.F.R. § 1001.952(a)-(x), set conditions that, if met, will not give rise to criminal or administrative action even if a culpable mental state is proven.

38. The HHS Secretary has promulgated two safe harbors potentially relevant in this action.

39. A litigant seeking to avail itself of AKS safe-harbor protection bears the burden of proving it satisfies one of the safe harbors. *See U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 98 (3d Cir. 2009).

40. Compliance with the AKS is a material condition of payment under federal insurance programs such that violating the AKS gives rise to a false claim. *See Westmoreland*, 812 F. Supp. 2d at 54 (collecting cases). In other words, a claim for payment made pursuant to an illegal kickback is false under the FCA. *U.S. ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 439 (3d Cir. 2004).

3. Personal Services Safe Harbor

41. The Personal Services Exception to AKS liability exempts personal services and management contracts from the definition of "remuneration" made "by a principal to an agent as compensation for the services of the agent" when *all* of the following elements are met:

(1) The agency agreement is set out in writing and signed by the parties.

(2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.

(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a fulltime basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

(4) The term of the agreement is for not less than one year.

(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arm's length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.

(7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

See 42 CF.R. § 1001.952(d)(6).

42. Under 42 C.F.R. § 1001.952(d)(6), services performed under an agreement that are conditioned on off-label use of a product do not qualify for the personal services and management safe harbor because they "involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal Law."

4. Discount Safe Harbor

43. The HHS Secretary has also exempted certain types of discounts from the definition of "remuneration" under the AKS so long as the seller "complies with the applicable standards in paragraph (h)(2) of this section." *Id.* § 1001.952(h). The Discount Exception applies to sellers when "[t]he seller is an individual or entity that supplies an item or service for which payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs to the buyer and who permits a discount to be taken off the buyer's purchase price." *Id.* § 1001.952(h)(2). To avail itself of the safe harbor's protection, the seller must meet *all* of the standards within one of three categories. *See id.* §§ 1001.952(h)(2)(i)-(iii) (imposing certain disclosure and reporting obligations).

44. "[T]he term discount means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction." *Id.* § 1001.952(h)(5).

45. "The term discount does *not* include— . . .

> (ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology."

Id. § 1001.952(h)(5)(ii).

46. The discount safe harbor does not apply to transactions for which the underlying discounts are not based on an arms-length, commercially reasonable transaction. *See* OIG Advisory Opinion No. 99-2 (Feb. 26, 1999). For example, an arrangement between a manufacturer and a provider for the purchase of a medical device does not qualify for the discount safe harbor when conditioned on off-label use of the device. "[I]f a price reduction is conditioned on more than the purchase of the product, then it is not a mere discount" but a form

of remuneration that brings it outside of the protection of the discount safe harbor. *See* United States Statement of Interest in *Herman v. Coloplast*, No. 11-12131 (D. Mass. Aug. 8, 2016).

5. OIG Compliance Program Guidance

47. The Office of the Inspector General of HHS ("OIG") has raised concerns about the payment of improper remuneration to providers under the guise of "educational grants" in its Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg 23731, 23734 (May 5, 2003) (the "OIG Guidelines").

48. The OIG Guidelines' section concerning "Relationships with Purchasers and their Agents" provides that "manufacturer grants to purchasers . . . raise concerns under the anti-kickback statute. . . . [where they are] conditioned, in whole or in part, on the purchase of product . . . even if the educational or research purpose is legitimate." *Id.* at 23735. "Furthermore, to the extent the manufacturer has any influence over the substance of an educational program or the presenter, there is a risk that the educational program may be used for inappropriate marketing purposes." *Id.*

49. OIG cautions manufacturers to "separate their grant making functions from their sales and marketing functions" to ensure that the funding is "not inappropriately influenced by sales or marketing motivations," that "the funded activities are *bona fide*," and that "the educational purposes of the grant are legitimate." *Id*.

6. FDA Restrictions on Off-Label Marketing

50. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., states that companies may not market medical devices in the United States without prior approval from the Food and Drug Administration ("FDA") for the device's intended use. 21 U.S.C. § 360. In order to market Class III devices, like those at issue in the present case,

manufacturers must submit a comprehensive application to the FDA for premarket approval. 21 U.S.C. § 360(e)(c).

51. Manufacturers can avoid the premarket approval process in two ways: the investigational device exception and the 510k clearance. The 510k clearance is based upon prior approval of a "substantially equivalent" device. 21 U.S.C. § 360; 21 C.F.R. § 807.87(k). The 510(k) clearance is not equivalent to FDA approval, and it limits cleared usage of the device to the intended indications listed in the application. 21 U.S.C. § 352(f); 21 C.F.R. §§ 801.5, 807.97. These indications must be listed on the label.

52. A manufacturer may only promote a device for cleared or approved indications. 21 U.S.C. § 352(f); 21 C.F.R. § 807.81(a)(3). Accordingly, promotion of a device for non-approved indications is considered "off-label" and is unlawful. 21 U.S.C. § 331(d). Though off-label use of medical devices by doctors is not *per se* unlawful, medical device manufacturers may not market such off-label use. *See, e.g.*, *Svidler v. U.S. Dep't of Health & Human Servs.*, No. C 03-3593, 2004 U.S. Dist. LEXIS 18325, at *14 (N.D. Cal. Jun. 10, 2004) ("[T]he FDA can restrict a company from marketing off label uses, but cannot prevent a doctor from prescribing a device for an off-label use for any purpose she deems medically necessary.") (*citing Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998)).

53. The use of medical devices for unapproved procedures is referred to as "off-label" use. Such off-label use that is not approved by the FDA may result in a negative impact to patients. For example, off-label use of medical procedures may expose patients to harm in the form of resulting complications, injuries, and even death.

54. For these reasons, the advertising or promotion of medical devices for purposes not approved by the FDA constitutes marketing of off-label use, also known as off-label marketing.

C. AtriCure's Atrial Fibrillation Medical Device Business

1. Treatment of AFib

55. Atrial fibrillation (also called AFib or AF) is a serious medical condition that is the most commonly treated type of heart arrhythmia. An arrhythmia occurs when the heart beats too slowly, too fast, or in an irregular way, and can lead to blood clots, stroke, heart failure and other heart-related complications. The CDC estimates that between 2.7 million and 6.1 million people in the United States have AFib.[1]

56. One method of treating AFib is a procedure known as Atrial fibrillation ablation. This is a type of cardiac ablation that works by scarring or destroying tissue in the heart muscle to disrupt faulty electrical signals causing the arrhythmia.[2] AtriCure's business and medical devices concern the treatment of AFib through surgical ablation.

57. Cardiac ablation refers to a class of procedures that strategically create lines of scar tissue to block transmission of the abnormal electrical signals that underlie atrial fibrillation. Cardiac ablation techniques include catheter ablation, Hybrid ablation, and "Cox Maze" surgery—which can either be open (concomitant, i.e., performed at the same time as another

[1] *See* https://www.cdc.gov/heartdisease/atrial_fibrillation.htm.

[2] *See* https://www.mayoclinic.org/tests-procedures/atrial-fibrillation-ablation/about/pac-20384969 (further describing three types of atrial fibrillation ablation).

heart procedure such as a bypass or a valve repair) or can be "minimally invasive" in a stand-alone procedure.[3]

58. Minimally invasive surgeries ("MIS"), generally, are those procedures undertaken in a manner that causes minimal trauma or injury to the patient, such as through a cannula using lasers, endoscopes, or laparoscopes. In the cardiac context, MIS typically denotes a procedure in which the patient's thoracic cavity is not opened.

59. AtriCure markets and promotes the use of its medical devices for Hybrid ablation and for minimally invasive Cox Maze surgery, despite the fact that its products have not been approved for MIS procedures.

60. Surgical ablation may be performed as either part of an open-chest procedure (often in conjunction with another open-chest, or "concomitant" procedure, such as a bypass or valve repair) or as a "minimally invasive" closed-chest procedure. During open chest surgical ablation, the surgeon opens the patient's chest through the sternum to make small incisions in the patient's heart tissue. The purpose of this procedure is to create scars that will provide a path for electrical signals in the patient's heart to follow. Open chest surgical ablations typically consist of what is referred to as a "maze" procedure or a variation of the Maze procedure.

61. During closed-chest MIS, surgeons cut small incisions on the sides of the patient's body and insert medical devices, such as those manufactured and sold by AtriCure, into the body in order to perform the procedures. The surgeon is unable to directly see the heart during the MIS procedures, and performs the surgery with the benefit of an endoscope.

[3] The "Maze" procedure for treatment of AFib, also interchangeably known as the "Cox Maze" procedure, is named for the surgeon who developed this technique, Dr. James L. Cox. *See* https://en.wikipedia.org/wiki/James_L._Cox. The procedure is described in further detail below.

62. Rather than with the benefit of direct visualization, MIS procedures are performed on the heart using a television monitor for visualization. As discussed throughout in this Third Amended Complaint, AtriCure's devices are not approved, or indicated, by the FDA for use in these MIS procedures.

63. Unlike catheter ablation procedures,[4] which are generally performed on an outpatient basis, surgical ablation procedures are performed on an inpatient basis, requiring the patient to stay in the hospital.

2. Open Chest Cardiac Maze (or Cox Maze) Procedures

64. The cardiac "maze" procedure is a form of open-chest surgery used to treat atrial fibrillation with strategic placement of incisions in both atria. Since its introduction, the maze procedure has undergone four iterations: Maze I, II, III, and IV, the first three of which involve cut and sew techniques used during open-chest procedures. These procedures utilize a "biatrial 'cut and sew'" technique in an attempt to guide the native sinus impulse to both the atria and the atrioventricular (AV) node while blocking all possible macroreentrant circuits. Various technical complications caused surgeons to further modify the original Cox Maze procedure, ultimately resulting in the Cox Maze III. The Cox Maze III eventually became the gold standard for

[4] In contrast, catheter ablation is another method for the treatment of cardiac arrhythmias. It is an outpatient procedure performed by an electrophysiologist in a catheterization lab. During catheter ablation, the surgeon inserts a thin, flexible tool—the catheter—into the heart during a closed-chest MIS. Once positioned, a machine delivers energy through the catheter to specific areas of the heart muscle that are causing the abnormal heart rhythm. This energy effectively disconnects the pathway responsible for the abnormality. During the procedure, the patient is typically placed under conscious sedation and goes home within one day of the procedure. The procedure has gained recognition as an effective atrial fibrillation treatment with low risk of complications caused by the procedure. *See* https://www.mayoclinic.org/tests-procedures/cardiac-ablation/about/pac-20384993.

treatment of atrial fibrillation using surgical ablation techniques, but remained relatively unpopular due to its complexity.[5]

65. In 2002, surgeons began replacing the Cox Maze III's incisions with "a combination of bipolar radiofrequency and cryothermal ablation lines." *Id.* This modified procedure was termed the Cox Maze IV. The Cox Maze IV procedure uses radiofrequency energy or cryoablation to create "transmural lesions" analogous to the lesions created by the more traditional cut and sew technique pioneered by the original Cox Maze procedure.

66. The Cox Maze IV lesions are similar to those of the Cox Maze III, but the procedure may be performed more quickly than the Cox Maze III, and may be performed concomitantly *or* in a minimally invasive procedure concomitant to another open chest procedure. The Cox Maze IV is a standard surgical procedure in the cardiology community that is reimbursed by Medicare and other government health insurance programs, when performed concomitantly.

3. Minimally Invasive Surgical Ablation

67. AtriCure's products are also sometimes used off-label for minimally invasive cardiac ablation in the form of MIS. minimally invasive surgical ablation or "thoracoscopic" Cox Maze procedures (*i.e.*, Cox Maze IV). As described above, the Cox Maze procedures are surgical procedures performed in the operating room with a patient under general anesthesia. The Cox Maze IV procedure is derivative of the original Cox Maze procedure but uses radio frequency (or other) energy to create lesions rather than a cut and sew technique like the original Cox Maze.

[5] *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904342/.

68. Open Chest Concomitant Maze procedures are an FDA-approved method of performing ablation procedures concomitant to other open-chest procedures, such as when the ablation is performed during another procedure like bypass surgery or heart valve repair. However, AtriCure improperly and unlawfully promotes its devices off-label for use in MIS procedures, including standalone MIS procedures.

69. A stand-alone, minimally invasive surgical ablation procedure—unlike traditional heart surgery—does not require opening the thoracic cavity to expose the heart and lungs and does not require putting the patient on a heart-lung bypass machine to stop the heart.

70. Minimally invasive cardiac procedures go by several different names, including the TT Maze (Totally Thoracoscopic Maze), the VAT or VATs Maze (Video Assisted Thoracic Maze), the MIS Maze (Minimally Invasive Surgery Maze), Hybrid Maze, the Mini Maze, and the Wolf Mini Maze. During these procedures, the surgeon threads a camera and surgical instruments through a small keyhole-sized incision between the ribs. Guided by a fiber optic camera, the surgeon then makes a series of lesions outside the heart using radiofrequency, energy, freezing, or ultrasonic energy.

71. These lesions are intended to destroy atrial tissue by causing scarring in areas known to conduct the electrical impulses that cause atrial fibrillation. When performed successfully on appropriate patients, the minimally invasive approach to the Maze procedure eliminates the need for dividing the breastbone (sternum), does not require the heart to be stopped, and does not require a heart-lung machine to be used. This often results in shorter recovery time and a lower risk of infection associated with open-chest surgery. Although AtriCure's devices are *not* FDA approved for these procedures, AtriCure has deemed it desirable

to market their devices for these off-label MIS procedures since many patients would prefer to avoid having an open chest surgery to treat their AFib condition.

4. **Off-Label AFib Treatments Using Specific AtriCure Products**

72. Defendants promoted AtriCure medical devices for use in atrial fibrillation procedures for which the devices were not FDA-approved in order to extend the reach of their illegal kickback scheme to a broader patient population.

73. AtriCure manufactures, markets, and sells a number of different devices for the treatment of Atrial Fibrillation (AFib) and related conditions by cardiothoracic surgeons and electrophysiologists. Among them are (i) clamps to occlude the left atrial appendage during surgery; (ii) tools to place the clamps on the left atrial appendage; (iii) tools to ablate heart tissue in order to block electrical impulses that cause atrial fibrillation; and (iv) tools to pass the ends of AtriCure Synergy clamps around the pulmonary veins in an MIS setting.

74. AtriCure's devices fall into the following product categories: RF Ablation, Pacing, and Sensing devices; Soft Tissue Dissection devices; Cyro devices; Left Atrial Appendage Management devices; Cart configurations; and Estech Valve Instrumentation.

75. Included among AtriCure's core business challenges during the Relevant Period were that (1) the vast majority of its products are only indicated for open-chest procedures; (2) uses of AtriCure's products are only reimbursable by Medicare and other government healthcare programs when used for such open-chest procedures or concomitant to other open-chest procedures; and (3) patients increasingly prefer the less invasive thoracoscopic, endoscopic, and laparoscopic procedures to open-chest procedures, and often are not well-informed of risks associated with off-label thoracoscopic procedures.

76. From the moment Relator began working at AtriCure, the company had been endorsing a staged "Hybrid Maze" procedure for treating persistent atrial fibrillation.[6] The Hybrid Maze procedure combines a minimally invasive Cox Maze IV procedure performed by a cardiac surgeon with a subsequent catheter ablation by an electrophysiologist. After a cardiac surgeon performs a minimally invasive Cox Maze IV lesion set, an electrophysiologist performs a catheter ablation by guiding a tube into the patient's heart to destroy pieces of cardiac tissue that are causing the abnormal heartbeat.

77. AtriCure's Hybrid Maze procedure was also the subject of its DEEP study, which is intended to evaluate the safety and effectiveness of such a procedure for patients with persistent or long-standing atrial fibrillation.[7]

78. While it is the practice of some surgeons to perform the catheter ablation immediately after the minimally invasive surgical procedure, some electrophysiologists perform the catheter ablation on a separate day. By combining both procedures, a full set of ablation lines can be performed, and incomplete ablation lines can be minimized.

79. AtriCure also manufactures and promotes the EPi-Sense Device for off-label standalone MIS procedures. The EPi-Sense Device is used as part of AtriCure's recommended "Convergent approach," involving the cutting of a small incision below the rib cage rather than opening the sternum. The Convergent approach refers to AtriCure's Epi/Endo ablation method for the treatment of persistent atrial fibrillation and is derived from the CONVERGE study, which was intended to evaluate the safety and efficacy of the EPi-Sense system for the treatment of certain symptomatic persistent AF patients.[8]

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[6] In October 2015, AtriCure purchased nContact, a company that marketed a similar procedure that was called the "nContact Convergent Procedure."
[7] *See* https://www.clinicaltrials.gov/ct2/show/NCT02393885?term=AtriCure.
[8] *See* https://www.AtriCure.com/converge-clinical-trial.

5. FDA-Approved Uses of AtriCure Products

80. AtriCure's devices are designed for, and are only indicated for (*i.e.*, approved for), open-chest surgical ablation procedures. They are only FDA-approved and reimbursable for MIS procedures when they are performed as a concomitant surgery. "Concomitant surgery" is a form of surgery in which a surgeon treats the atrial fibrillation "secondary, or concomitant, to a primary structural heart procedure such as a valve repair or replacement or coronary artery bypass graft (CABG)." Concomitant surgeries require open chest surgery as part of the covered procedure, in which the physician performs a sternotomy or other procedure to split open the patient's chest.

81. The following AtriCure products are approved solely for open-chest procedures: AtriClip Left Atrial Appendage (LAA) Exclusion System ("AtriClip Pro"), Isolator Synergy Ablation System, Fusion 150, Fusion 50, EMR2 Synergy Clamp, EML2 Synergy Clamp, Max5 RF Pen, MLP1 RF Pen, MRC1 Pen (Coolrail Linear Pen) and MID1 Wolf Dissector.

82. Among the AtriCure devices most commonly promoted and used off-label are the AtriClip Pro, Isolator Synergy Ablation System, Isolator Multifunctional Pen, Isolator Transpolar Pen System, Isolator Linear Pen, ACC2 and cryoICE BOX.

AtriCure's Violation of the Settlement Agreement and Corporate Integrity Agreement of February 2010

83. Rather than refrain from engaging in improper promotional practices as directed by the Government, Defendants unlawfully violated the terms of a federal Settlement and Corporate Integrity Agreements that imposed further restrictions on AtriCure's marketing practices resulting from past violations of those same FDA restrictions.

84. The United States and Plaintiff States have previously prosecuted AtriCure for violations of the False Claims Act. On February 1, 2010, AtriCure entered into a $3.77 million

Settlement Agreement with the DOJ and a Corporate Integrity Agreement[9] with OIG/HHS to resolve allegations that AtriCure caused the submission of false claims for reimbursement for over 2,000 MIS procedures performed using AtriCure products (the "2010 Settlement Agreement" and the "CIA").[10]

85. The 2010 Settlement Agreement's Covered Conduct specifically included:

> (1) that AtriCure caused false claims to be submitted by improperly instructing hospitals and other healthcare providers to code minimally invasive procedures using the AtriCure Ablation System, the AtriCure Bipolar System, and the AtriCure Transpolar System (collectively, "Ablation Devices") as "open" procedures when it knew such procedure codes were not correct;
>
> (2) that AtriCure promoted the sale and use of its Ablation Devices for the treatment of atrial fibrillation when it knew that such treatment was not medically necessary and knowingly caused false and/or fraudulent claims to be submitted to Medicare for such treatment;
>
> (3) that AtriCure caused false claims to be submitted by knowingly inducing hospitals to purchase its Ablation Devices by providing free or discounted marketing services and loaning or selling generators and disposable equipment to hospitals at less than fair market value; and
>
> (4) that AtriCure knowingly promoted the sale and use of its Ablation Devices for the treatment of atrial fibrillation, a use that has not been approved by the United States Food and Drug Administration, in violation of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a). Paragraph II.C.

86. In order to prevent future promotion of off-label uses of AtriCure's products, the CIA required, *inter alia*, AtriCure :

> a. to develop "appropriate ways to conduct Promotional and Product Services Related Functions in compliance" with "all applicable FDA requirements, including FDA regulatory approval requirements," as well as with "all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute . . . and the False Claims Act." CIA, Section III.B.2.b-c.
>
> b. to develop procedures concerning "the materials and information that may be distributed by AtriCure, Inc. sales representatives and account executives about

[9] The CIA was consummated on January 27, 2010 and expired by its terms on January 27, 2015.
[10] *See* https://oig.hhs.gov/fraud/cia/agreements/AtriCure_inc_01272010.pdf.

AtriCure, Inc.'s Government Reimbursed Products and the manner in which AtriCure, Inc.['s] sales representatives and account executives respond to requests for information about non-FDA approved (or 'off-label') uses of AtriCure, Inc.'s Government Reimbursed Products." CIA, Section III.B.2.d.

c. to train employees on "Federal healthcare program and FDA requirements relating to Promotional and Product Services Related Functions" and "examples of proper and improper practices related to Promotional and Product Services Related functions." CIA, Section III.C.2.e.

87. The CIA further required AtriCure to disclose any "Reportable Event" to OIG/HHS within 30 days after AtriCure determined that there was a Reportable Event. CIA, Section III.H. A "Reportable Event" is defined in the CIA as "anything that involves:"

i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the promotion of AtriCure, Inc. Government Reimbursed Products for which penalties or exclusion may be authorized; or

ii. the filing of a bankruptcy petition by AtriCure, Inc.

CIA, Section III.H.1.a.

88. As alleged herein, AtriCure all along planned to continue to engage in its fraudulent scheme even following settlement, in direct contravention of AtriCure's representations to the Government, even while in negotiations with the DOJ and HHS. AtriCure willfully concealed its promotional scheme from the Government by, among other things, entering into the 2010 Settlement and CIA it never intended to comply with and by failing to disclose reportable events once the CIA was entered into.

V. SUBSTANTIVE ALLEGATIONS

A. AtriCure Leveraged Kickbacks to Drive Reimbursement for Its Products

89. AtriCure offered and paid various forms of remuneration to hospital, surgeon, and EP customers in violation of the AKS. First, AtriCure paid kickbacks to individual providers in the form of cash payments, including under lucrative consulting agreements through which it paid hourly and event-based fees to select groups of surgeons and EPs. Second, AtriCure extended in-kind kickbacks to surgeons and EPs by paying third parties to perform consulting and professional credentialing and advertising services free of charge for these individuals in return for promoting AtriCure's products. Finally, AtriCure paid kickbacks to hospitals in the form of free capital equipment and free disposable medical device products, conditioned on further purchasing of AtriCure products.

1. Kickbacks to Individual Providers

90. AtriCure's business model focuses largely on offering surgeons lucrative agreements to induce them to use AtriCure products when performing AFib procedures. AtriCure sought to enter into agreements with surgeons who could perform both off-label and on-label procedures and had the potential to use a high volume of AtriCure products in their practices. While AtriCure entered into written agreements with surgeons, those agreements did not disclose all of the collateral understandings that AtriCure had with those surgeons as to their expected promotion of AtriCure products and procedures for which AtriCure products may be used.

91. AtriCure senior executives, including Kevin Henderson, Northwestern United States Sales Director, were responsible for recruiting surgeons and negotiating the terms of their agreements with them and/or their representatives. They often did so by inviting the surgeons to

visit Defendant St. Helena for a training or meeting (either directly or through AtriCure's sales or marketing staff), or by taking the surgeons to dinners, after which they would discuss the terms of potential agreements in private meetings.

92. During the Relevant Period, AtriCure entered into arrangements with numerous surgeons nationwide pursuant to which those surgeons were given cash and/or free products and services by AtriCure. These agreements called for action by the surgeons such as medical education engagements, trainings, and certain promotional-related activities. In return, AtriCure provided the surgeons dinners, free attendance at conferences, free products, and/or cash. A particular agreement could cover more than one type of arrangement, and individual surgeons frequently entered into more than one agreement.

93. Defendants used these agreements as vehicles to pay surgeons illegal kickbacks in the form of dinners, free attendance at conferences, free products, and renumeration for performing certain promotional-related activities.

94. For example, the surgeons and EPs in the following table each promoted and/or performed procedures using AtriCure products on behalf of the company and each received a total of at least $1,500 in their individual capacities from AtriCure between 2013 and 2018.[11]

[11] Industry reporting of financial remuneration for travel, gifts, and services rendered is now mandated by the US Centers for Medicare and Medicaid Services (CMS), and the resulting data are made publicly available through the Open Payments Program (OPP) database. *See* https://www.cms.gov/openpayments/.

LAST NAME	FIRST NAME	TOTAL	FACILITY	CITY	STATE
DUNNINGTON	GANSEVOORT	$ 1,037,747.63	Adventist Health - St. Helena	SAINT HELENA	CA
KHOYNEZHAD	ALI	$ 728,939.88	MemorialCare Medical Group -	LONG BEACH	CA
GERDISCH	MARC	$ 577,117.12	Franciscan St. Francis Heart Cent	DOWNERS GROVE	IN
OLSEN	CRAIG	$ 465,681.42	Cardiovascular & Chest Surgical	BOISE	ID
KISER	ANDY	$ 322,693.73	East Carolina Heart Institute at E	GREENVILLE	NC
JOHNKOSKI	JOHN	$ 139,574.92	Aspirus Heart & Lung Surgery	WAUSAU	WI
DAMIANO	RALPH	$ 82,147.77	Center for Advanced Medicine Heart & Vascular Center	ST. LOUIS	MO
EIFLING	MICHAEL	$ 41,131.58	McKay-Dee Heart Services	SALT LAKE CITY	UT
WHALEN	SEAN	$ 38,037.90	Vanderbilt Ingram Cancer Cente	NASHVILLE	TN
DIGIORGI	PAUL	$ 28,581.94	LPG Cardiothoracic Surgery	FORT MYERS	FL
CHANG-SING	PETER	$ 27,216.01	St. Joseph's Health	SANTA ROSA	CA
BELL THOMSON	JOHN	$ 18,996.55	Surgxl Cardiothoracic Services	EAST AURORA	NY
SVINARICH	JOHN	$ 16,790.84	St. Anthony's Hospital	LAKEWOOD	CO
BEAVER	THOMAS	$ 9,911.56	University of Florida Health	GAINESVILLE	FL
AFFLECK	DAVID	$ 7,123.83	MountainStar Cardiovascular Sur	SALT LAKE CITY	UT
REEVES	JUSTIN	$ 5,363.27	Providence Northwest Heart & L	SPOKANE	WA
MAHAN	BRYAN	$ 4,029.35	Boulder Community Health	BOULDER	CO
SPERLING	JASON	$ 3,927.54	HealthOne	AURORA	CO
MEHALL	JOHN	$ 2,526.99	Cardiac & Thoracic Surgery Assoc	COLORADO SPRINGS	CO
CONNORS	RAFE	$ 2,469.12	Intermountain Healthcare	SALT LAKE CITY	UT
KUMPATI	GANESH	$ 2,246.38	University of Utah Health	SALT LAKE CITY	UT
TRIPATHI	SANJAY	$ 1,877.15	Colorado Cardiovascular	DENVER	CO
DOTY	JOHN	$ 1,641.55	Intermountain Healthcare	MURRAY	UT

a. Consulting Agreements

95. AtriCure's illegal inducements included cash payments made to surgeons and EPs to utilize AtriCure devices and to appear on AtriCure's behalf at promotional events for the ostensible purpose of providing or receiving educational information. AtriCure entered into consulting agreements under which surgeons were paid an hourly or daily rate (typically $300 per hour or up to $1,500 per day) to provide training and/or educational services. These services included, among other things, speaking about AtriCure products, presenting at trade shows or conferences, and training physicians on how to conduct off-label procedures using AtriCure's products. Those agreements were called "Consulting Agreements."

96. At the center of AtriCure's Colorado hub, part of Relator's sales territory, is Dr. John R. Mehall, a cardiothoracic surgeon and Director of the Cardiac & Thoracic Surgery

Associates ("CTSA") physician practice. CTSA is affiliated with Penrose Hospital in Colorado Springs and St. Anthony Medical Center in Lakewood, Colorado.

97. Dr. Mehall is a key connector between AtriCure's activities in Colorado and its work on a national scale, including through Defendant St. Helena.

98. In 2015 and during other periods, Dr. Mehall was compensated under a Professional Services Agreement at the rate of $400 per hour for "hourly rate services" and between $750 and $4,000 for "fixed rate services," at a maximum of $15,000 annually. Dr. Mehall entered into this agreement under the auspices of, on information and belief, a shell company consisting solely of Dr. Mehall named "Advanced Clinical Training Association, Inc."

99. Similarly, on or about November 14, 2014, AtriCure entered into a "Consulting Agreement" with Dr. Michael Eifling . Under this agreement, Dr. Eifling would be paid between $300 per hour for Training Programs, Meetings and Presentations, Product Development Support, Group Meetings, Sponsored Research Groups, Business Development, Required Learning, and "Other Services," and $500 to $1500 per day for services such as acting as a Preceptor, Proctor, Training Program Chair, or Training Program Faculty, or engaging in AtriCure training or AtriCure training with travel.

100. AtriCure arranged these programs internally by email. In January 2016, Kevin Henderson requested from Diane Klausen "a standard consulting agreement" for Dr. Jason Sperling in Denver, Colorado because "Dr. Sperling is a high-volume center with easy access to our potential training targets out West." Kent Richards subsequently received an email from Relator stating that Dr. Sperling's practice was "approved as a training site."

101. Thus, AtriCure paid individual surgeons and electrophysiologists cash payments to utilize AtriCure devices (both off-label and on-label) and to appear on AtriCure's behalf at promotional events for the ostensible purpose of providing or receiving educational information.

102. For example, AtriCure conducted training events at Defendant St. Helena Hospital in St. Helena, California for physicians and others as a way to market AtriCure Products. AtriCure paid surgeons to attend these events, demonstrate procedures at cadaver labs, and make presentations. Kevin Henderson informed Relator that AtriCure paid St. Helena Hospital to hold these events in 2013. Specifically, Relator was informed that "you would be surprised how much we are paying St. Helena to do this. They are not doing this for free."

103. In addition, AtriCure paid surgeons to conduct clinical studies on AtriCure Products, and to provide post-market feedback regarding their use of AtriCure Products with their patients. AtriCure also paid surgeons for simply allowing AtriCure employees to observe surgeons performing procedures using AtriCure products.

104. AtriCure utilized consulting agreements and free services as vehicles to funnel payments to surgeons in order to induce them to use, or increase their usage of, AtriCure Products.

105. The company utilized potential paid consulting opportunities as a tool to attract new business from surgeons. For example, if AtriCure launched a new product, paid consultants were expected to give the product a look and assist getting the product on the shelf at the hospital for usage. The Relator was told on several occasions by Kevin Henderson to go see Dr. Affleck at St. Mark's in Salt Lake City, Utah and have him assist in getting new products into the hospital, which usually involves a new product committee that reviews the request and requires surgeon support.

106. None of these services provided by surgeons and EPs under the auspices of consulting agreements or grant programs satisfy the Personal Services safe harbor exception to AKS liability. See 42 CF.R. § 1001.952(d)(6).

b. Free In-Kind and Promotional Services

107. AtriCure paid surgeons and EPs illegal remuneration in the form of in-kind marketing and reimbursement services, including placement of customers on the prominent patient referral website at https://www.stopafib.org/ and in radio advertisements, and payment for the services of third-party coding and reimbursement specialist KBA, Inc.

108. At least one purpose of this scheme is to incentivize providers to use AtriCure products and perform AFib procedures using AtriCure products by offering to reduce or eliminate the cost of reimbursement services, marketing, referrals, and advertising.

109. Thus, these free services have real tangible economic value to providers beyond their utility in connection with the use of AtriCure products. As is true with respect to the Consulting Agreements discussed above, CMS has not excluded this conduct from AKS liability under any safe harbor. AtriCure likewise provides kickbacks to surgeons in the form of free advertising, press, and referral services to bring in more patients and business to the surgeons and to promote the surgeons as eminent physicians that provide cutting edge MIS procedures. This in-kind marketing support by sales representatives includes marketing to other physicians (i.e., primary care physicians, family practitioners) who can directly refer those newly diagnosed AFib patients to the cardiothoracic surgeons for surgery as a treatment option, thus eliminating the cardiologist, whose normal protocol for the treatment of atrial fibrillation is drug therapy and catheter ablation—all done as outpatient procedures.

110. By changing the normal course of referral patterns and replacing the referral to a cardiologist with direct referral to the cardiothoracic surgeon, the patient can then be referred for surgical ablation as a first line therapy instead of the outpatient therapy option that a cardiologist would provide for that same patient. The referral services also provide a valuable benefit to surgeons in marketing their practices generally, both including and apart from the surgical ablation procedures that generate purchases for AtriCure's products.

111. For example, in March 2015, AtriCure provided the Director of Marketing Communications and Business Development of AtriCure hospital customer St. Mark's with a "Public Service Address" to promote the services of St. Mark's surgeon Dr. David Affleck and his EP counterpart, Dr. Michael D. Eifling.

112. The public service announcement served as a "teaser" invitation to explore AFib procedures through St. Mark's and Drs. Affleck and Eifling, as follows:

> Hello . . . this is Dr. Smith in city. I'm happy to inform you that there are many treatment options for patients with atrial fibrillation. Over the past decade, therapy for atrial fibrillation has undergone dramatic changes. There are many medical, interventional and surgical treatments for patients with atrial fibrillation that did not even exist a few years ago. I strongly encourage you to contact your primary care physician to learn more about these options.

113. EPs and surgeons benefit from these public service announcements most directly, but the hospitals they practice at also benefit because AtriCure's surgical ablation procedures are performed on inpatients admitted at their facilities. Additionally, the public service advertisement and the StopAFib.org marketing incentives were often offered alongside AtriCure's other incentives, as shown below.

114. For example, on March 4, 2015, Danielle Wilcox of MountainStar Health emailed Relator, asking for an outline of short term and long terms marketing goals; the scripts for the radio advertisements that AtriCure proposed should be produced; "the budget that you'd

[AtriCure] like to allocate to this service"; and then asking to "proceed to the next step and schedule the peer-to-peer discussion." Later that day, Relator replied to Ms. Wilcox by an email titled "St. Mark's Marketing – Hybrid," copying Drs. Eifling and Affleck. In that email, Relator related AtriCure's marketing incentives:

(a) the peer-to-peer calls listed below are paid for by AtriCure. Also, we have a budget for patient education and outreach;

(b) I have attached the radio spot script to this email;

(c) Peer to Peer webinar with St. Helena Hospital currently on pace to do 100 hybrids this year (Ideally with Hospital Marketing, CFO, and Dr. Eifling and Dr. Affleck);

(d) Peer to Peer webinar with Dr. Andy Kiser on his AF program (Ideally with Hospital Marketing, CFO, and Dr. Eifling and Dr. Affleck)";

(e) Radio Ad – Public Service Announcement on AF (This is an easy marketing win);

(f) Billboard – you stated that you have an electronic billboard on Interstate 15 – we should get some AF/Hybrid messaging up there;

(g) StopAFib.org - #1 AF patient self-referral site on the web (Another easy win – currently only Dr. Affleck is listed on this site);

(h) U of Utah is dominating StopAFib.org, we need to get Dr. Eifling listed with photo & profile. Also maybe list the AF clinic at St. Mark's similar to what U of Utah has done;

(i) Understand reimbursement and make sure coding is being done correctly/Long Term Goals;

(j) PCP Referral Outreach Plan (My counterpart Kent Richards can help with this);

(k) Emergency Room AF patient tracking and referrals – you might have already done this;

(l) Get Accreditation – Society of Cardiovascular Patient Care AF Accreditation – you guys already have chest pain accreditation;

(m) AF Web Site Landing page that captures patient information on St. Mark's website;

(n) Dedicated Hybrid page on St. Mark's website – AtriCure can provide a ton of content;

(o) Patient Outreach Talks (AtriCure can help with the cost of these); and

(p) Patient videos – Local company in Denver (low cost – high quality production – click here to watch example of AFib Commercial).

115. Ms. Wilcox followed up on the above email on April 13, 2015 asking for "the content you mentioned you had for our website."

116. At about the same time in 2015, AtriCure's Kent Williams, Justin Noznesky, and Valerie Storch-Willhaus similarly worked to provide content for developing AFib websites, including copy, images, and links, including links to https://www.stopafib.org/, for hospitals in Salt Lake City and Denver.

117. A separate example of a coordinated effort further demonstrates AtriCure's ability and intention to provide promotional services to its partners that helped push uses for its AFib devices. On April 13, 2015, Kent Richards emailed Jon Gardner, Brenda Yost, and Maggie McMonigle of Centura Health under the title "Follow-up from April 10th Meeting." Mr. Richards forwarded a "slide presentation . . . that outlines the market for AF and the path to creating an integrated AF program . . ." and wrote that "[o]ther action items were for [AtriCure] to work on arranging a public service announcement for Drs. Tripathi and Sundarum with a local radio station and to look into potential educational grant opportunities."

118. The above meeting with Centura Health resulted in a PowerPoint entitled "AF Pathway," prepared by AtriCure and presented to Centura Health, that covered, among other things, "Marketing" and "awareness campaigns." The PowerPoint used Porter Adventist Hospital as an example of "certification" marketing ("Porter Adventist Hospital is the first and only hospital in Colorado to receive Atrial Fibrillation Certification"); St. Vincent Heart Center in

Indiana as an example of a "Center of Excellence"; and HealthOne in Denver, Colorado as an example of exclusivity ("New and Successful Treatment for Resistant or Persistent Forms of Atrial Fibrillation – Only at HealthOne").

119. The above PowerPoint for Centura Health also proposed "Local Public Service Announcements" including thirty second spots running "2-3 airings per week (free)" with a "script" as follows:

> Hello – This is Dr. Sundarum [or Tripathi, Mehall, etc.] from Denver. I am happy to inform you that there are many treatment options for patients with atrial fibrillation. Over the past decade, therapy for atrial fibrillation has undergone dramatic changes. There are many medical, interventional, and surgical treatments for patients with atrial fibrillation that did not even exist a few years ago. I strongly encourage you to contact your primary care physician to learn more about these options.

120. Underneath this "script" was a reference to "StopAFib.org," a photo and profile of a representative doctor (in this PowerPoint, the photo and profile of Dr. Mehall appeared), and a description of the National Alliance of Integrated AFib Centers ("NAIAC"). The PowerPoint concluded in part by saying the benefit of the above was establishing "Niche branding as an 'Atrial Fibrillation Treatment Center.'"

121. Following up on the Centura Health PowerPoint presentation, Kent Richards began the process of identifying radio stations on March 9, 2015 and April 13, 2015. On March 9, 2015, Richards contacted Crawford Broadcasting through https://crawfordmediagroup.net/, and inquired as follows:

> if there is any interest on your station's part in putting together a PSA for AFib using physicians in the Denver area? Let me know. Also . . . we might be interested in purchasing air space for a message, depending on the budget." On March 13, 2015, Richards contacted iHeartMedia.com, again asking, "I would like to find out if KOA does public service announcements. . . . [D]o you also do paid spots for optimum placement?

122. On April 30, 2015, Kent Richards emailed Relator a message titled "Atrial Fibrillation PSA – Dr. Robinson." Richards wrote, "I am taking next steps with KLZ. Trying to

give a couple of weeks lead time in order to get surgeon and EP together. Also have reached out again to KOA, this time going for straight advertising and not leading with PSA." On the same day, Richards again emailed. Titled "Radio Station Activity," Richards discussed pricing for advertisements at KZNT for the Colorado Springs market, KNUS (a sister station of KZNT), KLZ for the Denver market, KOA, KKZN, and KHOW also for the Denver market, and KEZW also for the Denver market, at which a local radio personality, Rick Crandle, would interview the physician customers for free.

123. Subsequently, on May 7, 2015, Richards emailed Kevin Henderson and Relator, writing "[h]ere is the script for the public service announcement (PSA). . . . The doctor can only use his name and not the name of the hospital. . . . We are able to pay for the spots."

124. Richards listed the prices as follows: KLZ for $25 per spot; and KEZW for $35 per spot or 72 commercials for $780. When Kevin Henderson asked by email, "Who is paying for it?" Richards replied, "I believe it would come out [sic] the West budget." Richards further wrote, "we could start with KEZW and see how it goes, then to KLZ. So our costs would only be $780."

125. On May 8, 2015, Richards emailed Amy Meyers and Relator. Titled "Website Content," the email tasked Ms. Meyers with creating a marketing kit for AtriCure's customers that would have "support for website content."

126. On the same day, May 8, 2015, Kent Richards emailed Dr. Sundaram in an email titled, "AFib Public Service Announcement," asking if Dr. Sundaram was available on May 14 to record the spot. Richards stated the spot would "be aired in 36 primetime spots."

127. Separate and apart from such coordinated activities as described above, AtriCure provided similar promotional services to other doctors, combined with other opportunities for

those doctors. For example, on June 10, 2015, Kent Richards, Area Manager, AF Program Development, sent Dr. Mehall of Centura Health an email titled "AF Projects at Penrose." The email stated that AtriCure wanted "to invite you and Dr. Cole to record an AF public service announcement at radio station KBIQ in Colorado Springs." Further, in this email, Richards began the leg work necessary to arrange a dinner in Colorado Springs with Dr. Mehall and Dr. Cole along with Dr. Khoynezhad (CT Surgeon) and Dr. Wang (EP) from Cedars-Sinai in Los Angeles.

128. AtriCure was willing to invest significant time and resources on promotional services. For example, on November 14, 2015, Ken Frazier, Senior Director of Clinical Development, emailed fourteen AtriCure managers and executives, including Kevin Henderson, President and CEO Michael Carrel, and COO Doug Seith. The email was titled "Fwd: Link to Fox Segment." Frazier wrote:

> All, thought you'd enjoy this video. This is one of our newest DEEP sites coming on board ([Clinical Project Manager] Marla Hoelle was there on Thursday) with Porter Adventist and Dr. Sri Sundaram. As a little background, [Relator] and I have been working with Dr. Sundaram (the EP) for over 3 years to get this up and rolling . . . and finally Dr. Tripathi has emerged as his Partner in this Hybrid procedure. This feels nice.

129. The above email of November 14, 2015 referenced an email dated October 27, 2015 titled "Re: TV Exposure" in which AtriCure assisted Dr. Sundaram in finding video footage of a surgery and ablation in preparation for his interview by the local Fox News affiliate in Denver.

130. AtriCure knew that the surgeon and EP beneficiaries of the free services would reliably promote AFib treatments utilizing AtriCure's devices.

c. Reimbursement Services

131. AtriCure paid a third-party reimbursement consultant Kathryn Barry & Associates, LLC ("KBA") to provide free reimbursement services to hospitals and physician practices. The business purpose of this service is made clear by Ms. Barry's request that AtriCure VP of Sales Keith Rundle have a representative of Saint Alphonsus Health System contact her to discuss a "hybrid program." The representative, Thom Reinhardt, was not a medical professional, but the hospital's Assistant Vice President for Cardiovascular Services & Business Development. Ms. Barry advised Mr. Rundle that Mr. Reinhardt had presented the AtriCure Hybrid Revenue document referred to above in order "to justify a hybrid program."[12]

132. AtriCure routinely paid KBA to help customers secure reimbursement for procedures using AtriCure devices.

133. Ms. Barry's and KBA's involvement at AtriCure with respect to billing and reimbursement was multi-faceted. For example, Relator has personal knowledge of receiving a PowerPoint presentation in 2011 during Relator's initial Sales Training titled "AtriCure Reimbursement Review.ppt." Relator has personal knowledge that the PowerPoint was presented by Kathryn Barry, who, as detailed above, is widely understood to be AtriCure's "go-to person" for billing questions.

[12] With respect to hybrid revenue referenced in the "hybrid revenue document," both the surgical procedure and the EP procedure that comprise a hybrid procedure are performed in a hospital. The "facility fee" is charged by the hospital, rather than an Ambulatory Surgical Center ("ASC"), for such procedures.

134. The PowerPoint's primary focus is billing and reimbursements, including but not limited to training AtriCure's sales representatives regarding how to communicate with doctors and hospital administrators about billing and reimbursement.

135. Specifically, starting on or about Slide 8 of Ms. Barry's powerpoint presentation, it is stated that AtriCure will help "appeal" any adverse reimbursement decisions. Relator's understanding of this Slide and its related Slides is that if a doctor performed a procedure using AtriCure devices and did not receive reimbursement, AtriCure would assist, behind the scenes, to obtain reimbursement from the government and private payers.

136. Ms. Barry and KBA were also closely integrated into AtriCure's work with both doctors and hospitals. For example, on March 20, 2015, Relator communicated with Dr. John Doty and Dr. Rafe Connor with an email titled "Kathryn Barry 3rd Party Reimbursement." Relator wrote, "Dr. Doty – here is Kathryn's contact info. All of her services are paid for by AtriCure." Dr. Doty specifically requested Ms. Barry's contact information again on April 14, 2015.

137. Similarly, on May 29, 2015, Kent Richards provided Ms. Barry's contact information to Jon Gardner in an email titled "Hybrid Maze Reimbursement (AtriCure)."

138. Ms. Barry also notified AtriCure executives when she provided information to hospitals on behalf of doctors. For example, on August 18, 2015, Ms. Barry spoke directly to James Kelley, the Administrator for Cardiac Surgery at the University of Utah, who was calling on behalf of a Dr. Kumpati of The University of Utah. Mr. Kelley and Dr. Kumpati sought LAA coding information. After providing the coding information, Ms. Barry emailed Keith Rundle, AtriCure's Area Vice President, Western U.S., to inform him that she had provided the information to Mr. Kelley and to Dr. Kumpati.

139. AtriCure sales representatives applied Ms. Barry's reimbursement training, described above, while in the field. For example, on March 31, 2016, Relator emailed Kerstein Zabukovic of Valley View Medical Center in Glenwood Springs, Colorado. Under the title "Kerstein – nContact Convergent Procedure with Cyro Balloon", Relator wrote "[p]er our conversation, here is the information for Kay regarding the procedure that Dr. Stout and Dr. Glatterer would like to do in the near future. . . . We would like to set up a call with a 3rd party reimbursement specialist so that the hospital can understand the financials of this procedure." The preparation for the above call began on March 24, 2016 when Relator emailed KBA associates. Titled "Kathryn – Reimbursement Call 3/31." That email referenced "Valley View Medical Center in Glenwood Springs, Colorado."

140. Ms. Barry was responsive when AtriCure had a reimbursement issue with respect to an important account. For example, on March 11, 2016, Chad Tucker, Manager of the Heart and Vascular Institute at McKay Dee Hospital in Ogden, Utah, emailed Kevin Henderson, Stacey Hendrix, Tanner Cox, and Relator under the title "AtriCure Product." Mr. Tucker wrote,

> Kevin . . . the procedure can't be done until our internal research committee approves the study. We know it will be approved however it won't be approved by the committee until April. I was instructed not to purchase these items until approval. . . . In the meantime I would like to get the billing process set up. Do you have the CPT codes for the hospital? I would like to compare the codes and the potential charges. Not the numbers but what is allowed by most insurance companies. [For] [e]xample can I do both procedures at the same time? The same day? Is it better for the patient and for billing to do this on separate days[?] Can you send me the codes for both processes and a little guidance on the appropriate way to bill these procedures.

141. On the same day, March 11, 2016, Kevin Henderson responded with an email to Kathryn Barry stating, "I copied you on a message below as this customer needs some help coding and billing the Convergent procedure. They are a huge customer of ours in Utah. Please keep me informed as you work with them." The referenced copied message, from Mr. Henderson

to Mr. Tucker on the same day, identified Ms. Barry as "the 3rd party coding specialist we discussed. Please reach out to Kathryn as she can help answer all of your billing and coding questions."

142. In response to the above emails, Ms. Barry responded by email on March 13, 2016 by writing, "I would be happy to help. In reply, please see the attached document (titled 'AtriCure's Health Policy Consultant Coding Considerations Document'). The codes for surgical maze with concomitant cath ablation are listed in the attached document. Upon review, let me know if there are any questions." Ms. Barry signed her email by name above the title "Health Policy Consultant for AtriCure."

143. With respect to this particular set of coding questions from the above account, Mr. Henderson also sent a 10:54 p.m. email to Relator on March 11, 2016, indicating that Mr. Henderson had in part diffused the issue by calling Mr. Tucker. Mr. Henderson wrote in his 10:54 p.m. email, "I just got off the phone with Chad. I will also send a text to Melman to have him call me." This communication was on private email, not work email.

2. **Kickbacks to Institutions**

144. Defendants conceived of and implemented a comprehensive, nationwide and interconnected scheme to pay various forms of remuneration to hospital systems like Centura Health and Defendant Adventist Health and the hospitals within those systems, to promote and perform certain procedures using AtriCure products. AtriCure's kickbacks to surgeons and EPs described above were designed principally to deliver as customers the institutions that purchased the bulk of AtriCure's products and in which the in-patient procedures were performed.

145. AtriCure developed Defendant St. Helena as an "Integrated AF Program," and sought to create others. On July 10, 2015, Mr. Richards advised Doug Boudreaux,

MountainStar/St. Mark's VP of Marketing and Government Relations that there was a "tremendous opportunity" for it to "brand as specialty centers for AFib treatment."

146. Defendant St. Helena and the EP associated with the target institution in question routinely served as access points for these efforts. In one representative example, in September 2015, when Mr. Richards was advised that St. Mark's surgeon Vijay Jayankar had been introduced to Dr. Eifling at a St. Helena training event, Mr. Richards advised Relator that "this may be what we need to get the program rolling" at "St. Mark's/MountainStar."

a. Grant Program

147. Defendants St. Helena and Adventist solicited from Defendant AtriCure, and in turn Defendant AtriCure agreed to pay (and did pay), Defendant St. Helena and Defendant Adventist illegal remuneration in exchange for inducing sales of its products to Medicare and other government payers under the guise of cash "grants" ostensibly relating to patient education and professional training.

148. In exchange for illegal kickbacks from AtriCure, under the Educational Grants program, hospitals, including Defendants St. Helena and Adventists engaged in illicit promotion using materials designed and/or funded by AtriCure.

149. Educational grants were documented as individual letter agreements under which the hospitals purportedly agreed to provide educational content regarding the use of AtriCure's products either directly to patients or to the medical community. The educational content designed and/or funded by AtriCure was intended to convince surgeons and EPs, and their hospital affiliates, to use AtriCure products.

150. It was commonly known at AtriCure that the giving of grants was directly tied to sales potential. While educational personnel like VP of Professional Education & Clinical

Science Michael Rogge sat on the grant committee, in order to ensure grants were based on sales potential, the principal decisionmakers on the committee were sales and marketing executives, including AF Program Development Area Manager Kent Richards and Northwest Director of Sales Kevin Henderson.

151. Approved by management, sales and marketing personnel gave large sums in "grants" to medical facilities and physician practices ostensibly for educational programs and/or research programs. The grants have actually been used to provide kickbacks to these facilities and practices to do whatever they wanted with the money, in return for business.

152. AtriCure sales representatives were to identify hospitals amenable using AtriCure products for certain procedures, and to offer potential grants to incentivize growth. For example, upon identifying such a hospital, the AtriCure sales representative would tell the hospital that it could receive an AtriCure "grant" for patient education once the hospital started doing off-label procedures, to assist the hospital in increasing off-label case volume. The sales representative walked the hospital through the steps of applying for the grant, which ostensibly was decided by an AtriCure grant committee independent of the sales and marketing teams. Grants could be awarded out of sales and marketing budgets as well, separate from grant committee grants.

153. While AtriCure sales representatives and marketing teams were not supposed to be involved in the AtriCure grant process, in fact they were often involved in several aspects of the process.

154. Grants for hospitals performing off-label procedures were specially marked for approval for the AtriCure grant committee and as a result were rarely turned down by the grant committee.

155. As with other facets of AtriCure's kickback schemes, as discussed above, many of AtriCure's communications with respect to grants were coordinated through phone, text message, or private email—not work email.

156. Upon a hospital submitting a grant proposal, the sales representative would communicate with the Area Director (e.g., Kevin Henderson), who would then communicate with COO Doug Seith that the grant should be approved because it concerned a hybrid account, which was understood to be an account worth, or potentially worth, significant revenue.

157. Upon information and belief, COO Doug Seith would then communicate within AtriCure, including the grant committee, as needed to have the grant approved. Sandy Ponder, Manager of Professional Education Programs, is believed to have been an internal liaison for these communications.

158. The Grant Committee's true purpose was to provide remuneration to hospitals and those affiliated with them in exchange for promoting AtriCure products. For example, Relator has personal knowledge of a "patient education grant" awarded for an event on March 4 through 6, 2016 at a ski resort in Beaver Creek, Colorado. At this event, no patients were present. Instead, the event was for the benefit of Dr. Mehall, Dr. Sundaram, and Dr. Cole, each of whom were established, high-revenue AFib producers, and each of whom were paid AtriCure consultants. The attendees of the event were referring physicians, i.e., doctors who were sending or would send referral cases to Drs. Mehall, Sundaram, and Cole. This grant was sought and in part secured by Kathy Camasta of Cardiac and Thoracic Surgery Associates ("CTSA") in Colorado Springs, Colorado.

159. The underlying mechanics to award the above grant were as follows. On August 8, 2015, Dr. Mehall emailed Ken Frazier, Relator, and Dr. Thomas Beaver inviting them on

behalf of CTSA to sponsor the March 4-6 event. Dr. Mehall wrote, "We are planning on having a session about AF and I have already asked Dr. Tom Beaver to speak about the Hybrid procedure and results to date." In turn, on August 10, 2015, Ken Frazier emailed Michael Rogge that Dr. Mehall "is interested in AtriCure to fund [sic] this Educational event that will supply CME's. Since you are the educational guru, this should fit in nicely with your team." Emails inside AtriCure on this subject were titled "CTSA Cardiovascular Summit – March 4-6, 2016 – Grant Request," including a November 30, 2015 email from Michael Rogge to Kevin Henderson, Keith Rundle, and Relator confirming that "the attached meeting sponsorship for Dr. Mehall's CV Summit has been approved. Looks like a great meeting!"

160. Then on November 29, 2015, Kathy Camasta of CTSA emailed Michael Rogge, also inviting AtriCure to provide "grant sponsorship" to its March 4 through 6, 2016 CTSA Cardiovascular Summit at the Westin Hotel in Beaver Creek, Colorado.

161. The next day, on November 30, 2015, Michael Rogge emailed Justin Noznesky and Terrie Holahan, stating that "Justin and I have exchanged messages with regard to the attached support in the amount of $5k. Justin has agreed to fund this from the regional tradeshow budget." Later that day, Terrie Holahan emailed Lindsay Wagoner, Kevin Henderson, and Keith Rundle, and Relator, confirming that "Mike Rogge and Justin have approved attending at the $5k level."

162. The above event for which CTSA secured a grant from AtriCure discussed off-label topics relating to "New AF Treatments & Hybrid Procedures for AF." The specific off-label agenda items at this event sponsored by AtriCure for $5,000 were (1) "New Atrial Fibrillation Treatments and Guidelines" from 5:20 p.m. to 5:40 p.m.; and (2) "Hybrid MAZE

Procedure for Stand Alone AF" from 5:40 p.m. to 6:00 p.m. Over 20 surgeons and doctors attended this event.

163. AtriCure's teams also coordinated other similar grants. For example, Kent Richards emailed Kevin Henderson, Sandy Porter, and Relator on April 29, 2015, to assist Penrose Hospital in Colorado Springs, Colorado obtain a grant from AtriCure. In addition, on May 6, 2015, Jordan Velare of CTSA requested from AtriCure another CTSA grant (distinct from the grant discussed above), this time to sponsor a five-part education series titled "CTSA Cardiac Surgery Talks." On June 26, 2015, Michael Rogge, VP of Professional Education & Clinical Science, communicated with Relator, copying Sandy Ponder, in an email titled "CTSA Outreach Penrose, Co." writing that "we reviewed the $5k grant proposal for Dr. Mehall's group to do AF patient education/outreach. . . . [And] the grant committee agreed to a $2500 grant." On July 1, 2016, Sandy Ponder communicated the approval to Mr. Velare.

164. AtriCure provided another such grant in January or February 2016, when it sponsored a program in early February 2016 at the Society of Thoracic Surgeons regarding LAA management. As part of sponsoring the program, AtriCure approved an "education grant" to sponsor an on-demand webcast by five doctors titled "Why the LAA Matters: The Role of LAA Occlusion for Stroke Management." The on-demand webcast covered topics including "AtriClip: Results of Clinical Trials." Relator is aware that another topic that the webcast covered was "MIS Left Atrial Appendage Management." Relator has personal knowledge that AtriCure sales representatives were expected to secure the attendance of surgeons and EPs so that they would be encouraged to start MIS LAA programs of their own at their respective hospitals.

165. AtriCure's method of maximize the reach of this grant was similar to that used to leverage the CTSA grant described above. On November 13, 2015 Justin Nozensky, VP of

Marketing, communicated with the entire AtriCure sales force, the Executive Leadership Team, and the Marketing Group. Among other things, Mr. Nozensky stated that "AtriCure is supporting the program through an educational grant to the sponsor….We will also be sending out a comprehensive STS plan and summary as we get closer to the show."

166. Subsequently, on February 23, 2016, Kevin Henderson communicated with the entire Northwest sales team, requesting that sales representatives work to ensure their surgeons watched the LAA presentation. He wrote,"[p]lease make sure you get this to your surgeons. Great opportunity to provide value with this CME event in the privacy of their office or home."

b. <u>Free Products and Equipment</u>

167. AtriCure routinely provide kickbacks to hospitals in the form of free products or the free use of equipment, disguised in the form of discounts or equipment loans. AtriCure's free products enable hospitals to reduce their costs and increase reimbursement on each procedure performed. The hospital receives a windfall of 100% of the value of these free products because DRG-based reimbursement to the hospital is fixed.

168. None of these arrangements satisfy the discount safe harbor as the free items are often given on the explicit condition that the hospital will predominantly (or exclusively) use AtriCure's products.[13]

169. AtriCure's free products provided to hospitals and clinics, include: (a) capital equipment such as generators used to power AtriCure's disposable equipment and cardiac mapping units such as AtriCure's ORLab cardiac mapping system, used in conjunction with that

[13] *See* United States Statement of Interest in *Herman v. Coloplast*, No. 11-12131 (D. Mass. Aug. 8, 2016) ("[I]f a price reduction is conditioned on more than the purchase of the product, then it is not a mere discount" but a form of remuneration that brings it outside of the protection of the discount safe harbor).

equipment (and priced by AtriCure at $50,000); and (b) disposable equipment used to perform surgical ablations such as scopes, clamps and trays.

170. AtriCure extended what it referred to as "no charge" loans of capital equipment, which often also served as free replacements of competitors' capital equipment, in exchange for the purchase of disposables by the facility.

171. Disposable products were likewise given as gifts, often in exchange for the hospital's agreement to buy a targeted volume of Defendants' products and/or to give Defendants' products preferred status.

172. When providing free products to customers, AtriCure dispatched a sales representative to carry the products to their destinations personally rather than to ship the products by mail. This occurred even when free products were provided as part of a bundle of discounted or retail-priced products. All products other than free products were shipped to their destinations as per standard practice.

173. With regard to capital equipment, AtriCure routinely provided customers with free hardware, such as a free generator, cardiac mapping equipment, and even laptop computers, in exchange for purchases of disposables used in off-label procedures and for preferred product status at the facility. These inducements typically took the form of so-called "no charge loans" of capital equipment, including free replacements of competitors' incompatible capital equipment.

174. While AtriCure sales representatives referred to the medical equipment it provided to hospitals and physicians as "loaners," in reality, there was no loan; the equipment was given as a gift. Frequently clients were also provided with a highly valuable service maintenance agreement at no charge, to provide additional financial incentives.

175. For example, Kevin Henderson communicated with Chad Tucker on March 8, 2016, copying Relator. In an email titled "AtriCure Quote UT041107", Henderson referenced "the quote for the nContact products" and noted that "[a] no charge PO would be required for the ablation hardware needed."

176. The March 8, 2016 invoice provided to the McKay-Dee Hospital Center listed three nContact products with price quotes: two Epi-Sense Guided 6130 Device sets (one 3-Pack at $44,985 and one 5-Pack at $74,975) and a "Subtle Cannual with Guide Kit" ($3,500).

177. The invoice also listed two items with quote prices of zero, a "Generator Kit – RF" and an "RF External Graphic Display PC Kit (laptop). The invoice documents that both of the free items were '[p]laced at hospital per a signed loaner agreement and no charge PO."

178. AtriCure sales representatives would "permanently loan" medical equipment to a hospital with no intention of ever receiving compensation for it in a variety of circumstances, such as in order to prevent customers form switching to a competitor. On other occasions, sales representatives gave away the medical equipment as a "promotion" or as a "demo unit," or as part of its "customer relations."

179. For example, as discussed *supra*, in March 2015, AtriCure offered representatives at Porter Adventist Hospital discount pricing on several "MIS products" for use by paid AtriCure consultant Dr. Sanjay Tripathi, including the AtriClip Pro. At the time the offer was made, AtriCure already had two cases scheduled with Dr. Tripathi. Porter Adventist Hospital was also advised that AtriCure would "hold onto the AtriClip Pros until Dr. Tripathi's next case, but whatever size clip he uses, it will be free."

180. On March 30, 2015, Jonathan Just of Centura Health confirmed that Porter Adventist fully understood that AtriCure's pricing agreement was "to be used with the ORLab equipment" for which the hospital had "signed a loaner agreement."

181. Another "loaner agreement" example transpired in May, June, and July 2015. On May 5, 2015, Teresa Clark of AtriCure Customer Service emailed to Relator "the one-year pricing agreement for the disposables, the quote for the capital equipment, and the ELA loaner agreement for the capital equipment." On May 8, 2015, Relator provided St. Anthony's Hospital RN, Barbara Ferguson, in Denver with documents AtriCure needed and requested that they be "returned to AtriCure to get St. Anthony's set up in our system."

182. Subsequently, on July 30, 2015, David Sharon of Centura emailed Relator and Dana Underwood of St. Anthony Hospital in Denver under the title "AtriCure Loaner Agreement for Capital & Pricing Agreement." Mr. Sharon attached three "New Account CO St. Anthony's Hospital" documents, including a "[o]ne Year Pricing Agreement" document. On that same day, July 30, 2015, Sharon also wrote to Relator that "[o]ur buyers will contact you with [a] no-charge PO and have the signed agreements next week."

183. Later that same day, Relator emailed Barbara Ferguson of St. Anthony Hospital in Denver stating, "[w]e never received the loaner agreement back for our machines. We also never received the signed pricing agreement back as well. You guys purchased disposables this week but you don't have any machines (Radio Frequency & Cyro) to use our disposables. We need the signed agreements back and a no charge PO for the ASU, ASB, ACM, and Simple Cart System."

184. In another representative example, on July 2, 2015, AtriCure issued a "No Charge PO" to Andrew Smith of Intermountain Medical Center in Murray, Utah for an ORLab cardiac

stimulator, cryoICE BOX console and AtriCure System Cart. The "PO Price" for each of these items was quoted at zero.

185. With respect to disposable equipment, a representative example of AtriCure providing such equipment for free in exchange for using AtriCure products may be found in a series of emails exchanged between AtriCure and Centura Health regarding Porter Adventist Hospital in Denver, Colorado. In an email on December 21, 2015, Centura Health Business Manager Mr. Just confirms his assent to receiving five of ten cases of AtriCure disposable products (including EMR2s, EML2s, Max5s and MLP1s[14]) from AtriCure "for free." The products would be used for procedures performed at Porter Adventist.

186. Mr. Just's prior December 16, 2015 email had requested that Relator "hand carry 5 of each free ones [sic] directly to my office" with "[t]otal savings = $50K." In the same email, Mr. Just explained that "these are all bundled because all get used for the Vats maze cases that are being marketed right now for Dr. Tripathi."

187. "VATS maze" is an abbreviation for the off-label "Video Assisted Thoracoscopic Surgery" maze procedure. Dr. Sanjay Tripathi was a paid AtriCure consultant with Porter Adventist.

188. In a January 12, 2016 follow-up email, Mr. Just asked Relator whether AtriCure "delivered the no-charge product yet? (qty: 5)."

189. In March, 2015, in a string of emails titled "Jill/Nancy – AtriCure Pricing Agreement", Relator communicated with Mr. Just and Centura Health RN Jill Goossen of Centura Health about another bundled deal. In these emails, dated March 30, 2015, Relator

[14] The EMR2, EML2, Max5 and MLP1 are abbreviations for AtriCure's Isolator Endo-Synergy Clamps (right and left) (approximately $3,000 each), Isolator Long Pen TT (approximately $2,000), and Isolator Linear Pen, 20mm electrode (approximately $2,500) respectively.

wrote, "Jon – Here is the quote you requested. After you place the PO, I will carry the other items into Jill next week (EMR2, EML2, Max5, MLP1) – don't list the no charge items out on the PO. I will hold on the AtriClip Pros until Dr. Tripathi's next case but whatever size he uses, it will be free." AtriCure prices the AtriClip Pro at approximately $2,000 each.

190. Six months later, on September 22, 2015, regarding more product, Mr. Just emailed Relator asking, "[i]s the process the same as last time, where we issue the PO for a qty of 3, and you hand carry in the free product?"

E. AtriCure Knew Its Products Caused Patient Harm

191. On January 22, 2018, AtriCure published an "URGENT Advisory Notice" regarding the "AtriCure COBRA Fusion Ablation System Instructions for Use (IFU) Update Due to Thromboembolic Event Occurrences." This two-page document stated that "AtriCure has identified a potential safety issue regarding thromboembolic events (TE) occurring in cardiac surgical procedures using the COBRA Fusion device."[15]

192. This document also stated, "AtriCure has received 35 reports of thromboembolic events (34 strokes and 1 Transient Ischemic Attack (TIA)) since worldwide introduction of the device in March 2012." The document indicated that, going forward under the Instructions For Use (IFU) Update, the Cobra fusion device should be used under modified warnings and modified precautions. Specifically identified were three Cobra Fusion 150 catalog numbers and one Cobra Fusion 50 catalog number. As the referenced document indicates, the Cobra Fusion 150 device is still in use.

[15] AtriCure's Cobra ablation system consists of a radio-frequency power generator known as an electrosurgical sensing unit ("ESU"), which uses radiofrequency energy to heat tissue and is used in conjunction with surgical probes to create lesion sets for the treatment of atrial fibrillation. The Cobra ablation system can be used either in conjunction with open chest surgery or as a stand-alone minimally invasive procedure.

193. With respect to reporting by AtriCure of adverse events to the FDA's MAUDE system, anomalies occurred in August 2018, when, as to its Fusion 150 product, AtriCure suddenly reported nine adverse events that in fact had occurred not in 2018 but rather in the years 2015 and 2016, including during MIS procedures.

194. Separate and apart from the nine adverse events regarding the Fusion 150 in the years 2015 and 2016 that AtriCure did not report to the FDA's MAUDE system until August 2018, AtriCure was directly and immediately aware of adverse events regarding its Fusion 150 product as early as 2013.

195. For example, on January 9, 2014, AtriCure emails indicate that AtriCure management and executives learned of a Fusion 150 adverse event at St. Mark's Hospital in Salt Lake City, Utah occurring on December 31, 2013. The adverse event involved a Medicare eligible 68-year-old female. With respect to this 2013 adverse event, Dr. David Affleck reported to AtriCure that the "patient had a post-op stroke" which included paralysis of her arm. Within days, Kevin Henderson, Director of Western Sales, forwarded Dr. Affleck's report of this adverse event to Kevin Rundle, Area Vice President, and Doug Seith, Chief Operator Officer. The procedure was identified as an MIS Cardiac Tissue Ablation. Subsequently, on December 3 and December 6, 2015, AtriCure's Kevin Carlston, Barry Bagley, Nina Christophersen, Relator, and Nina Ashcraft, Complaint Coordinator, communicated by email under the title "Fusion/Stroke Case." The emails discussed that "it has been brought to our attention we have another Fusion/Stroke case," indicating that AtriCure knew of multiple other Fusion/Stroke cases by that time. The emails also discussed that any details of other such cases were needed because "[t]his information is very important as we have a timeline to meet in order to report these incidents to the FDA."

196. As AtriCure was learning of the above specific adverse events in real-time starting as early as 2013, AtriCure was also receiving broad reports from surgeons regarding patient harm caused by the Fusion 150 device, including when used in MIS procedures. For example, on November 17, 2017, AtriCure reported the following as an adverse event on the FDA's MAUDE system: "An AtriCure representative attended the Fusion Summit held in [location] where a slide presentation on a paper was given: Staged hybrid ablation for long standing persistent atrial fibrillation. During the conference, one of the surgeons from [location] stated that approximately over a 3-year period, 12 events that involved the Fusion 150 device where the patients had phrenic nerve injuries associated with the procedure. The surgeon theorized that the back of the device overheats and stated that this may have contributed to such injuries. This view was not shared by most of the participants of the meeting and were previously reported to the FDA on 13 Apr 2016."

197. Despite knowledge of the foregoing adverse events, AtriCure formed a Fusion Advisory Board during this time period to promote the Fusion 150 device. For example, in an email dated July 27, 2015, titled "FW: Fusion Advisory Board Lunch Meeting, August 29," Sandy Ponder communicated with John McDonough, Jerrad Giomi, Michelle Brust, Wally Sordo, and Relator that "The invite for the Fusion Advisory Board Meeting went to the list of surgeons below." The doctors listed were "Dr. Bell-Thomson – confirmed, Dr. Dunnington – not available, Dr. Affleck, Dr. Sakwa, Dr. DiGiorgi." A related email indicated that this particular Board meeting took place in Chapel Hill, North Carolina, in conjunction with an "ISMICS Show."

198. Emails indicate that one of the reasons AtriCure continued to promote the Fusion 150 during this time period, despite knowledge of patient harm, was because the Fusion 150

required other AtriCure products to be purchased along with it when used off-label. For example, in emails dated May 6 and May 19, 2015, Erin Hartz communicated with Jack Wesley, Senior Director, Product Development, and the entire AtriCure sales force. In an email titled "Minimally Invasive Fusion 150," Ms. Hartz informed Mr. Wesley and the sales force that "When using the Cobra Fusion 150 in Minimally Invasive procedures the Magnetic Introducer System must be ordered along with the Cobra Fusion 150 device." She then listed the "Magnetic Introducer System, Fusion 150, Ground Pads, Suction Canister, ESU-Generator, and Medela Suction Pump. . . . for ALL non-Sternotomy procedures when using the Fusion 150 and 50.

199. Upon information and belief, as a result of AtriCure's continued promotion of the Fusion 150 device, including for off-label procedures, an increasing number of surgeons began adding the Fusion 150 product to their MIS product suite during cases in this time period, despite the growing number of adverse events related to the Fusion 150 device.

200. With respect to the specific harm caused by the Fusion 150, AtriCure possessed increasing knowledge during this time period that the strokes suffered by patients in procedures using the Fusion 150 device arose as a result of blood clotting. AtriCure also possessed increasing knowledge that the clotting was caused by temperatures generated by the Fusion 150 during procedures.

201. Specifically, AtriCure possessed increasing knowledge that the Fusion 150 device, which sucks atrial tissue up into the device and then ablates the tissue, was also sucking blood into the device, consequently burning not just the targeted tissue but also the surrounding blood, which then caused clots, which in turn caused strokes. During this time period AtriCure possessed increasing knowledge that the above patient harm arising from use of the Fusion 150 device would particularly occur during MIS Cardiac Tissue Ablation procedures. In response,

AtriCure instructed its sales teams to advise surgeons to alter and/or adjust the temperature settings that were set in the Fusion 150 device. AtriCure also instructed its sales teams to advise surgeons to "heparinize" their patients with additional amounts of Heparin before the Fusion 150 device started to unnecessarily burn adjacent blood during ablation.

202. Relator has personal knowledge that, with respect to the above, AtriCure told its sales representatives in the field that COO Doug Seith was working on the issue. Relator also has personal knowledge of a conversation with Jack Wesley, AtriCure's Clinical Director, in which Mr. Wesley informed Relator that AtriCure was making changes to the temperature of the Fusion 150 device.

203. Consequently, upon information and belief, AtriCure made, or attempted to make, a material change to the temperature control technology of the Fusion 150 device without first obtaining a 510k from the FDA or without first issuing a product recall.

204. In addition to the above, Mr. Wesley informed Relator that AtriCure was advising surgeons to administer more Heparin to patients prior to using the Fusion 150 device in procedures. Mr. Wesley then informed Relator to keep the conversation between them (Mr. Wesley and Relator) via text message.

205. Relator is aware that, as result of the above issues regarding the Fusion 150, individuals in AtriCure's sales force believed that patients were being harmed and that AtriCure management was attempting to mask the extent of the patient harm.

206. Relator is aware that the majority of surgeons using the Fusion 150 device during procedures in this time period were paid consultants of AtriCure, as discussed above, and consequently AtriCure had the capability to more easily mask the above issues that resulted in patient harm.

F. Defendants' Conduct Caused False Claims To Be Submitted To The Government

207. As alleged herein, Defendants knowingly engaged in several interconnected fraudulent kickback schemes that caused false claims for reimbursement of the costs of medical procedures and AtriCure products used for those procedures to be submitted to government purchasers.

208. Second, AtriCure's illegal kickbacks from 2010 to the present caused government health programs to pay for AtriCure products used in, among other procedures, the off-label hybrid maze procedure, standalone MIS procedure, and staggered hybrid procedure alleged herein as the subject of the thirty-day scheme.

209. In order to promote the economic benefits of the hybrid maze procedure to providers, AtriCure internally prepared and disseminated the following spreadsheet entitled "Hybrid Revenue." The spreadsheet explained to hospitals and physicians the manner in which the hybrid procedure would be reimbursed by Medicare and was intended to promote it over alternative treatments.

Most Common 2-Stage AFIB Ablation Scenario

EP Mapping followed by Thoracoscopic Approach using Atricure materials, LAA Exclusion as Stage 1.
EP lab Catheter ablation as stage 2. Medicare Patient.

	ICD	CPT	DRG	Description	Medicare Reimbursement
PRESTAGE 1: EP Assessment/Mapping					
EP Lab mapping & patient assessment		93620-26		Comprehensive EP evaluation, including catheter placements	$ 611
Mapping packaged with 93656		93613		3D Mapping electrical circuitry of heart pre-surgery	$ -
Add-on codes as applicable				Several add-on codes are available	
SECTION SUBTOTAL					$ 611
STAGE 1: CVOR Ablation + LAA Exclusion					
STAGE 1 of Hybrid: CVOR portion - facility fee	37.37		229	Thoracoscopic approach: AFIB Ablation	$ 26,340
STAGE 1 of Hybrid: CVOR portion - pro fee	37.37	33266		Thoracoscopic approach: AFIB Ablation	$ 1,742
LAA closure packaged with DRG 229	37.36			LAA Closure (atriclip or suture)	$ -
SECTION SUBTOTAL					$ 28,082
STAGE 2: EP Assessment/Mapping/Ablation					
Facility fee	37.34	93656		Comprehensive EP evaluation, including catheter placements	$ 13,613
Profee	37.34	93656		Tx atrial fib Pulm Vein Isolation	$ 1,064
EP Assessment		93662.26		Intracardiac ecg (ice)	$ 140
3D Mapping		93613		3D Mapping electrical circuitry of heart pre-surgery	
Add-on codes as applicable				Several add-on codes are available	
SECTION SUBTOTAL					$ 14,677
GRAND TOTAL					$ 43,370

210. The spreadsheet refers to the hybrid procedure as the "Most Common 2-Stage AFIB Ablation Scenario."

211. The spreadsheet identifies three reimbursement stages, corresponding with the EP's initial assessment (Stage 1), the cardiothoracic surgeon's procedure (Stage 2), and the EP's procedure (Stage 3).

212. Medicare reimburses EPs approximately $610 for Stage 1 via CPT Codes 93620-26.

213. Medicare reimburses hospitals approximately $28,000 for Stage 2 via DRG Code 229.

214. Medicare reimburses cardiothoracic surgeons approximately $1,700 for the professional fee component of CPT code 33266.

215. Medicare reimburses hospitals approximately $13,000 for Stage 3 via the Facility Fee component of CPT 93656.

216. Medicare reimburses EPS approximately $1,200 via the Professional Fee component of CPT Code 93656 and for CPT Code 93613.

217. As alleged herein, AtriCure representatives covering the Northwest Territory were among the participants in the company's illegal promotional scheme. Included among them were Kris Gouveia and Jerrad Giomi covering parts of California, Kevin Carlson covering parts of Oregon, Washington state and Idaho, and David Lee covering parts of Washington state.

218. AtriCure's internal sales data set forth in a March 10, 2016 document entitled "Leader Board Summary – MIS" reflects that these sales representatives collectively generated nearly $900,000 in revenue derived from MIS procedures during Q1 2016 alone.

219. Also, in March 2016, Minimally Invasive Manager Christie Carlson circulated an internal AtriCure spreadsheet entitled "Northwest MIM Account Target List" to Mr. Henderson, copying the Northwest Team, including Relator, Mr. Gouvera, Mr. Giomi, Mr. Carlston, and others.

220. The MIM ("Minimally Invasive Manager") Target List spreadsheet included columns entitled "Annual MIM Target Volume 2017" and "Target for EOY 2016."

221. The MIM sales tracked in this spreadsheet explicitly referenced both hybrid maze and Convergent MIS procedures.

222. Mr. Carlston generated $233,279 in MIS sales during Q1 2016

223. Mr. Carlston's Target Volume 2017 and Target for EOY 2016 for MIS sales were $3.99 million and $1.39 million, respectively.

224. The MIM Account Target List also reflects that Mr. Carlston's territory generated approximately $280,000 in "YTD MIM Sales."

225. The off-label Convergent training that took place at Rose Medical Center in Denver on February 12, 2016 is specifically mentioned in the MIM Target List spreadsheet. Among the visitors scheduled to attend the training were EP Dr. Ramu Redy and CT surgeon Dr. David Duke, from Mr. Carlston's assigned hospitals in Oregon.

226. AtriCure's Target for EOY 2016 MIS sales for Mr. Carlston's Sacred Heart Riverbend hospital alone, where Drs. Reddy and Duke are residents, was $240,450, consisting of twenty-one off-label Convergent procedures.

227. Mr. Gouveia's territory generated $196,331 in MIS sales during Q1 2016.

228. Mr. Gouveia's Target Volume 2017 and Target for EOY 2016 were $4.03 million and $982,500 in MIS sales, respectively.

229. Among Mr. Gouveia's hospitals was a VA hospital in San Francisco. AtriCure's Target for EOY 2016 MIS sales for this VA hospital alone was $155,000, including for eight off-label convergent procedures scheduled for the remainder of the year. For 2017, the VA hospital was scheduled to complete two Convergent procedures per month. The spreadsheet further states that the San Francisco hospital is a "[g]reat account for [Convergent procedures] due to a large number of VA patients who have AFib."

230. Mr. Giomi's territory generated $380,031 in MIS sales during Q1 2016

231. Mr. Giomi's Target Volume 2017 and Target for EOY 2016 MIS sales were $3.28 million and $2.16 million, respectively.

232. The MIM Account Target List also shows Mr. Giomi's approximately $380,000 in MIS sales, identified as "YTD MIM Sales."

233. Mr. Giomi was responsible for sales through Defendant St. Helena, where both Drs. Dunnington and Bing Liem were residents.

234. As alleged herein, Dr. Dunnington was the recipient of over $1 million in total payments from AtriCure in his individual capacity between 2013 and 2018.

CAUSES OF ACTION

COUNT I
False Claims Act
31 U.S.C. §3729(a)(l)(A)

(False Claims)

235. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

236. By virtue of the acts described above, Defendants knowingly submitted, caused to be submitted and continue to submit and cause to be submitted false or fraudulent claims for payment and reimbursement by the United States Government. The United States, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices, and violations of the False Claims Act.

237. As set forth in the preceding paragraphs, Defendants violated 31 U.S.C. § 3729 and have thereby damaged and continue to damage the Government by their actions in an amount to be determined at trial.

COUNT II
False Claims Act
31 U.S.C. §3729(a)(1)(B)
(False Records)

238. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

239. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims submitted or

caused to be submitted for payment and reimbursement by the United States Government. The United States, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices, and violations of the False Claims Act.

240. As a result of such conduct, Defendants violated 31 U.S.C. § 3729, *et seq.*, and have thereby damaged and continue to damage the Government by their actions in amounts to be determined at trial.

COUNT III
False Claims Act
31 U.S.C. § 3729 (a)(1)(C)

(Conspiracy)

241. Relator realleges and reincorporates all the preceding paragraphs of the Complaint as if fully set forth herein.

242. By virtue of the acts described above, Defendants, together with others known and unknown, conspired to violate the False Claims Act by knowingly and willfully submitting or causing the submission of false or fraudulent claims for payment or approval by the United States Government, and by knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims submitted or caused to be submitted for payment and reimbursement by the United States Government. The United States, unaware of Defendants' conspiratorial conduct with regard to falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices, and violations of the False Claims Act.

243. As a result of such conduct, Defendants violated 31 U.S.C. § 3729, *et seq.*, and have thereby damaged and continue to damage the Government by their actions in amounts to be determined at trial.

COUNT IV
California False Claims Act
Cal. Govt Code §12651(a)(1) and (2)

244. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

245. This is a claim for treble damages and penalties under the California False Claims Act.

246. By virtue of the acts described above, Defendants knowingly presented or caused to be presented false or fraudulent claims to the California State Government for payment or approval.

247. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

248. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continue to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

249. By reason of Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

250. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

251. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of California in the operation of its Medicaid program.

COUNT V
Violation of the Colorado Medicaid False Claims Act
Colo. Rev. Stat. § 25.5-4-305

252. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

253. This is a claim for treble damages and penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-303., *et seq*.

254. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

255. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

256. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

257. By reason of Defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

258. The State of Colorado is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

259. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Colorado in the operation of its Medicaid program.

COUNT VI
Violation of the Connecticut False Claims Act for Medical Assistance Programs
Conn. Gen. Stat. § 17b-301b

260. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

261. This is a claim for treble damages and penalties under the Connecticut Medicaid False Claims Act, Conn. Gen. Stat. § 17-b-301a, *et seq*.

262. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval.

263. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut State Government to approve and pay such false and fraudulent claims.

264. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

265. By reason of Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

266. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

267. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Connecticut in the operation of its Medicaid program.

COUNT VII
Violation of the Delaware False Claims and Reporting Act
6 Del. C. §1201(a)(1) and (2)

268. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

269. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act.

270. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

271. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

272. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

273. By reason of Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

274. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

275. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

COUNT VIII
Violation of the Florida False Claims Act
Fla. Stat. Ann. §68.082(2)

276. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

277. This is a claim for treble damages and penalties under the Florida False Claims Act, Fla. Stat. Ann. §68.081, *et seq*.

278. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

279. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

280. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

281. By reason of Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

282. The State of Florida is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

283. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

COUNT IX
Violation of the Georgia State False Medicaid Claims Act
Ga. Code Ann. § 49-4-168.1 *et seq.*

284. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

285. This is a claim for treble damages and penalties under the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1 *et seq.*

286. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

287. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

288. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

289. By reason of Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

290. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

291. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

COUNT X
Violation of the Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)

292. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

293. This is a claim for treble damages and penalties under the Hawaii False Claims Act, Haw. Rev. Stat. §661, *et seq.*

294. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

295. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

296. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

297. By reason of Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

298. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

299. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

COUNT XI
Violation of the Illinois Whistleblower Reward and Protection Act (as amended)
740 Ill. Comp. Stat. §175/3(a)(1), (2)

300. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

301. This is a claim for treble damages and penalties under the under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*, as amended.

302. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

303. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

304. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

305. By reason of Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

306. The State of Illinois is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

307. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

COUNT XII
Violation of the Indiana False Claims and Whistleblower Protection Act
IC 5-11-5.5 *et seq.*

308. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

309. This is a claim for treble damages and penalties under the under the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5 *et seq.*

310. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

311. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

312. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

313. By reason of Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

314. The State of Indiana is entitled to the maximum penalty of $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

315. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

COUNT XIII
Violation of the Iowa False Claims Act
Iowa Code § 685.2

316. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

317. This is a claim for treble damages and penalties under the under the Iowa False Claims Act, Iowa Code §§ 685.1 *et seq*.

318. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Iowa State Government for payment or approval.

319. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Iowa State Government to approve and pay such false and fraudulent claims.

320. The Iowa State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

321. By reason of Defendants' acts, the State of Iowa has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

322. The State of Iowa is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

323. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Iowa in the operation of its Medicaid program.

COUNT XIV
Violation of the Louisiana Medical Assistance Programs Integrity Law
La Rev. Stat. Ann § 46:438.3

324. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

325. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law, La Rev. Stat. Ann § 46:437.1 *et seq*.

326. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

327. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

328. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

329. By reason of Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

330. The State of Louisiana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

331. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

COUNT XV
Violation of the Maryland False Health Claims Act
MD Code Ann. § 2-602

332. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

333. This is a claim for treble damages and penalties under the Maryland False Health Claims Act, Annotated Code of Maryland § 2-601 *et seq*.

334. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

335. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

336. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

337. By reason of Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

338. The State of Maryland is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

339. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Maryland in the operation of its Medicaid program.

COUNT XVI
Violation of the Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(1), (2)

340. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

341. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

342. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts Commonwealth Government for payment or approval.

343. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts Commonwealth Government to approve and pay such false and fraudulent claims.

344. The Massachusetts Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

345. By reason of Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

346. The Commonwealth of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

347. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

COUNT XVII
Violation of the Michigan Medicaid False Claim Act
MCL 400.607

348. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

349. This is a claim for treble damages and penalties under the Michigan Medicaid False Claim Act, MCL 400.601 *et seq.*

350. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

351. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

352. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

353. By reason of Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

354. The State of Michigan is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

355. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

COUNT XVIII
Violation of the Minnesota False Claim Act
Minn. Stat. § 15C.02

356. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

357. This is a claim for treble damages and penalties under the Minnesota False Claim Act, Minn. Stat. § 15C.01 *et seq.*

358. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Minnesota State Government for payment or approval.

359. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Minnesota State Government to approve and pay such false and fraudulent claims.

360. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

361. By reason of Defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

362. The State of Minnesota is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

363. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Minnesota in the operation of its Medicaid program.

COUNT XIX
Violation of the Montana False Claims Act
MCA § 17-8-403

364. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

365. This is a claim for treble damages and penalties under the Montana False Claims Act, MCA § 17-8-401 *et seq.*

366. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

367. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

368. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

369. By reason of Defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

370. The State of Montana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

371. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

COUNT XX
Violation of the Nevada False Claims Act
Nev. Rev. Stat. Ann. §§ 357.040(1)(a), (b)

372. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

373. This is a claim for treble damages and penalties under the Nevada False Claims Act.

374. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

375. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

376. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

377. By reason of Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

378. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

379. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

COUNT XXI
Violation of the New Hampshire False Claims Act
N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

380. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

381. This is a claim for treble damages and penalties under the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

382. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

383. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

384. By reason of Defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

385. The State of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

386. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

COUNT XXII
Violation of the New Jersey False Claims Act
N.J.S.A. 2A:32C-3

387. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

388. This is a claim for treble damages and penalties under the New Jersey False Claims Act, N.J.S.A. 2A:32C-1 *et seq.*

389. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

390. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

391. By reason of Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

392. The State of New Jersey is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

393. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

COUNT XXIII
Violations of the New Mexico Medicaid False Claims Act, N. M. S. A. 1978, §§ 27-14-1 *et seq.* and the New Mexico Fraud Against Taxpayers Act, N. M. S. A. 1978, §§ 44-9-1 *et seq.*

394. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

395. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act, N. M. S. A. 1978, § 27-14-1 *et seq.* and the New Mexico Fraud Against Taxpayers Act, N. M. S. A. 1978, § 44-9-1 *et seq.*

396. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

397. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

398. By reason of Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

399. The State of New Mexico is entitled to the maximum penalty under of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

400. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

COUNT XXIV
Violation of the New York False Claims Act
N.Y. State Finance Law § 189

401. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

402. This is a claim for treble damages and civil penalties under the New York False Claims Act, NY State Finance Law § 187 *et seq.*

403. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

404. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

405. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

406. By reason of Defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

407. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

408. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

COUNT XXV
Violation of the North Carolina False Claims Act
N.C.G.S. § 1-607

409. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

410. This is a claim for double damages and penalties under the under the North Carolina False Claims Act, N.C.G.S. § 1-605 *et seq.*

411. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina Government for payment or approval.

412. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

413. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

414. By reason of the Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

415. The State of North Carolina is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

416. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of North Carolina in the operation of its Medicaid program.

COUNT XXVI
Violation of the Oklahoma Medicaid False Claims Act
63 Okl. St. Ann. § 5053.1

417. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

418. This is a claim for double damages and penalties under the under the Oklahoma Medicaid False Claims Act, 63 Okl. St. Ann. § 5053 *et seq.*

419. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

420. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

421. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

422. By reason of Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

423. The State of Oklahoma is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

424. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

COUNT XXVII
Violation of the Rhode Island State False Claims Act
R.I. Gen. Laws § 9-1.1-3

425. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

426. This is a claim for double damages and penalties under the under the Rhode Island State False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*

427. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

428. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

429. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

430. By reason of Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

431. The State of Rhode Island is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

432. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

COUNT XXVIII
Violation of the Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)

433. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

434. This is a claim for double damages and penalties under the under the Tennessee Medicaid False Claims Law.

435. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

436. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

437. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

438. By reason of Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

439. The State of Tennessee is entitled to the maximum penalty of $25,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

440. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

COUNT XXIX
Violation of the Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. § 36.002

441. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

442. This is a claim for double damages and penalties under the under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

443. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

444. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

445. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

446. By reason of Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

447. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

448. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

COUNT XXX
Violation of the Vermont False Claims Act
32 V.S.A. § 630 *et seq.*

449. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

450. This is a claim for double damages and penalties under the under the Vermont False Claims Act 32 V.S.A. § 630 *et seq*.

451. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Vermont State Government for payment or approval.

452. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

453. The Vermont State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

454. By reason of Defendants' acts, the State of Vermont has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

455. The State of Vermont is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

456. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Vermont in the operation of its Medicaid program.

COUNT XXXI
Violation of the Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3(A)(1), (2)

457. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

458. This is a claim for treble damages and penalties under the under the Virginia Fraud Against Taxpayers Act Va. Code Ann. § 8.01-216.1 *et seq.*

459. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia Commonwealth Government for payment or approval.

460. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia Commonwealth Government to approve and pay such false and fraudulent claims.

461. The Virginia Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

462. By reason of Defendants' acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

463. The Commonwealth of Virginia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

464. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

COUNT XXXII
Violation of the Washington State Medicaid Fraud False Claims Act
RCW 74.66.020(1)

465. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

466. This is a claim for treble damages and penalties under the under the Washington State Medicaid Fraud False Claims Act, Revised Code of Washington 74.66.005 *et seq.*

467. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Washington State Government for payment or approval.

468. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Washington State Government to approve and pay such false and fraudulent claims.

469. The Washington State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

470. By reason of the Defendants' acts, the State of Washington has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

471. The State of Washington is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

472. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Washington in the operation of its Medicaid program.

COUNT XXXIII
Violation of the District of Columbia Procurement Reform Amendment Act
D.C. Code Ann. §1-1188.14(a)(1), (2)

473. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

474. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §2-381.01 *et seq*.

475. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

476. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

477. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

478. By reason of Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

479. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

480. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

COUNT XXXIV
Violation of the Allegheny County False Claims Act
§ 485-1 *et seq*.

481. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

482. This is a claim for treble damages and penalties under the Allegheny False Claims Act § 485-1 *et seq*.

483. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Allegheny County Government for payment or approval.

484. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Allegheny County Government to approve and pay such false and fraudulent claims.

485. The Allegheny County Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

486. By reason of Defendants' acts, the County of Allegheny has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

487. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the County of Allegheny in the operation of its Medicaid program.

COUNT XXXV
Violation of the Chicago False Claims Act
Chi. Mun. Code Ch. 1-22-020(1-2))

488. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

489. This is a claim for treble damages and penalties under the Chicago False Claims Act, Chi. Mun. Code Ch. 1-22-020(1-2).

490. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the City of Chicago Government for payment or approval.

491. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City of Chicago Government to approve and pay such false and fraudulent claims.

492. The City of Chicago Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

493. By reason of Defendants' acts, the City of Chicago has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

494. The City of Chicago is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

495. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the City of Chicago in the operation of its Medicaid program.

COUNT XXXVI
Violation of the City of New York False Claims Act
Local Law 53, Chapter 8 § 7-801 *et seq.*

496. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

497. This is a claim for treble damages and penalties under the City of New York False Claims Act, Local Law 53, Chapter 8 § 7-801 *et seq*.

498. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the City of New York Government for payment or approval.

499. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City of New York Government to approve and pay such false and fraudulent claims.

500. The City of New York Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

501. By reason of Defendants' acts, the City of New York has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

502. The City of New York is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

503. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the City of New York in the operation of its Medicaid program.

COUNT XXXVII
Violation of the Philadelphia False Claims Act
§ 19-3601 *et seq.*

504. Relator realleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

505. This is a claim for treble damages and penalties under the Philadelphia False Claims Act, § 19-3601 *et seq*.

506. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the City of Philadelphia Government for payment or approval.

507. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City of Philadelphia Government to approve and pay such false and fraudulent claims.

508. The City of Philadelphia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

509. By reason of Defendants' acts, the City of Philadelphia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of himself and the United States Government, and the respective state, county and municipal governments under whose law and on whose behalf he also brings this action, respectfully prays as follows:

1. That for violations of the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, this Court enter Judgment against Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus the maximum civil penalties allowed by law for each and every action in violation of 31 U.S.C. § 3729, *et seq*.

2. That for violations of the respective state, county and municipal False Claims Acts as alleged herein, this Court enter Judgment against Defendants in an amount equal to the maximum amount of damages each governmental entity has sustained because of Defendants' actions, including such multiples of damages as allowed by statute or code, plus the maximum civil penalties allowed by law for each and every action in violation of such statutes or codes.

3. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and the respective state, county and municipal False Claims Acts as alleged herein, including the costs and expenses of this action and reasonable attorneys' fees.

4. That a trial by jury be held on all issues; and

5. That the United States Government, the respective represented state, county and municipal governments, and Relator, receive all relief, both in law and equity, to which they reasonably are entitled.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby requests a trial by jury.

Dated: August 6, 2021

Respectfully submitted:

/s/ Matthew D. Quinn
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Attorneys for the Plaintiff-Relator Joel Stevens

CERTIFICATE OF SERVICE

I hereby certify that on August 6, 2021 the foregoing document (including exhibits, if any) was electronically filed with the District Court using the CM/ECF system, which provided notice to all counsel of record. In addition, copies of the foregoing document (including exhibits, if any) was served by U.S. Mail addressed to the following non-CM/ECF participants:

William Tong Connecticut Attorney General Connecticut Office of the Attorney General 55 Elm St. Hartford, CT 06106	Ashley Moody Florida Attorney General Office of The Florida Attorney General Medicaid Fraud Control Unit The Capitol PL-01 Tallahassee, FL 32399-1050
Jeff Landry Louisiana Attorney General Louisiana Department of Justice 1885 N. Third Street Baton Rouge, LA 70802	Mike Hunter Attorney General of Oklahoma Office of the Oklahoma Attorney General 313 N.E. 21st St. Oklahoma City, OK 73105
Mark R. Herring Virginia Attorney General Virginia Office of the Attorney General 202 N. 9th Street Richmond, VA 23219	Bob Ferguson Washington Attorney General Washington Office of the Attorney General 1125 Washington St. SE Olympia, WA 98504

Additionally, I hereby certify that on August 6, 2021 the foregoing document (including exhibits, if any) was served via email upon the following non-CM/ECF participants:

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/s/ Matthew D. Quinn
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